The development, piloting and evaluation of a bra intervention for women with larger breasts who are experiencing breast pain

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Abstract

Breast pain is a prevalent condition in the UK (52%) which can negatively impact women’s quality of life. Research identified that bras can effectively reduce breast pain in women with larger breasts, yet, no randomised controlled trial has been conducted, despite bras being recommended as a treatment. Previous research reports that one bra design may not be suitable for all women with larger breasts indicating that bras should be specific to the individual. Within a clinical environment, based on Medical Research Council guidelines, the overall aim of this thesis was to develop, pilot and evaluate a bra intervention for women with larger breasts who are experiencing breast pain.

As with other populations of women, the appropriateness of a bra for this cohort is likely to be multifactorial, influenced by both subjective and objective variables. Therefore, the first study, used a focus group and interviews to determine the performance variables for assessing bra appropriateness.

Due to the substantial choice available within the UK lingerie market, these bra performance variables were used to develop a novel bra selection criteria which was applied to the UK lingerie market in study two and resulted in the selection of six everyday bras for assessment within the bra intervention study.

Chapter Four, then identified four key bra performance variables from study one (comfort, support, fit and aesthetics) and used these to develop methods (subjective and objective) to individually prescribe one of the bras.

In Chapter Five, a review of literature and pilot investigations identified the methods for assessing the effectiveness of the bra intervention including determining three important outcome measures; the Patient’s Global Impression of Change Scale, a Numerical Rating Scale (breast pain intensity) and the SF-36 (quality of life).

Having developed all aspects of the bra intervention, study three then piloted this intervention using the Queen Alexandra Hospital Portsmouth as a recruitment site. Patients were randomly assigned to either the standard care group or the intervention group where patients had a bra individually prescribed, and then wore this bra for eight weeks. Outcome measures were assessed at four and eight weeks. Recruitment (n = 34) and retention of patients was poor (33% drop out in the bra prescription group and 50% drop out in the standard care group), however, a significant improvement in quality of life ($\chi^2 = 8.667, P = 0.010$) was identified within the bra prescription group. Evaluation of this bra intervention suggested that there were barriers to patient participation.

Study four investigated these barriers for this population. Less than half of patients surveyed (43%) were interested in the bra prescription, perhaps because 84% felt they were wearing...
a well-fitting bra, despite study three identifying that 91% of patients within the bra prescription group were not wearing a well-fitting bra. Aside from this, time constraints were the largest barrier to participation.

Study five was a comparative survey-based study with non-clinic cohorts. The pregnant and breastfeeding group (82%) and younger adults group (72%) were the most likely to report they would take up the bra prescription service. Fewer women felt they were wearing well-fitting bras (range = 55% to 83%), possibly explaining the high level of interest. Time constraints continued to be a barrier to participating. The outcomes of this study suggests that those within the clinical population need further education to ensure they understand the benefits of appropriately fitting bras.

In conclusion, this was the first study to develop, pilot and evaluate a bra intervention using a bra prescription for women with larger breasts and breast pain. This study established a framework for prescribing a bra, which could be applied to other populations. Although the efficacy of the intervention was inconclusive due to a low sample size, there was a positive impact on quality of life. The intervention should therefore be developed further. With the current population there should be a focus on educating patients on appropriate bra fit in order to encourage them to utilise such a service. The trial should then be re-run as an observation or patient-preference trial, to understand the effect of the bra prescription on breast pain, prior to re-running the randomised controlled trial. Alternatively, the bra intervention could be refocused on a non-clinic population, such as pregnant and breastfeeding women, who are more likely to take up the bra prescription.
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Declaration Page

Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

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Abbreviations

DSES – Department of Sport and Exercise Science
EPO – Evening Primrose Oil
ICC – Intra-class Correlation
KPI – Key Performance Indicators
k h⁻¹ – kilometres per hour
MCS – Mental Component Summary
MRC – Medical Research Council
NHS – National Health Service
NRS – Numerical Rating Scale
PCS – Physical Component Summary
PGIC – Patient Global Impression of Change
PHT – Portsmouth Hospitals Trust
QA – Queen Alexandra
QoL – Quality of Life
ROM – Range of Motion
SD – Standard Deviation
SF-36 – 36 item Short Form Health Survey
VAS – Visual Analogue Scale
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1 Chapter One: Introduction

1.1 Review of literature

1.1.1 Breast anatomy

The breast sits anteriorly on the chest wall between the second and sixth ribs (Gefen & Dilmoney, 2007). The breast covers a large area and extends laterally from the medial point of the sternum to the latissimus dorsi underneath the axilla and vertically it extends as far as the clavicle (Gefen & Dilmoney, 2007). The breast is a complex structure mostly consisting of interweaving fat and glandular tissues, the proportion of each type of tissue varies between women, and changes across a woman’s lifespan (Hassiotou & Geddes, 2013). The tissues are located within the superficial fascia surrounding the inner tissues of the breast anteriorly (Lemaine & Simmons, 2013). The deep fascia sits posteriorly to the glandular and fat tissue and anteriorly to the pectoralis major muscle (Lemaine & Simmons, 2013; Riggio, Quattrone, & Nava, 2000). Internally, the support for the fatty and glandular tissue is suggested to come from weak fibrous connective tissue called Cooper’s Ligaments and collagen fibres (Gefen & Dilmoney, 2007) and externally by the skin (Page & Steele, 1999). Bras are often recommended as a form of external support (Bowles, Steele, & Munro, 2008).

The breast undergoes most developmental changes (for example, breast mass increases) during puberty, although changes also occur across the menstrual cycle and during pregnancy (Hassiotou & Geddes, 2013; Howard & Gusterson, 2000). Cyclical breast pain relates closely to the menstrual cycle, and this suggests that it is important to understand how the breast changes as these changes may influence the occurrence of breast pain and the treatment provided.

1.1.2 Pain

To appreciate the principles of breast pain fully, it is important that the mechanisms associated with general chronic pain, the types of pain and the physiological process which make humans feel pain, are understood. There are three main types of pain; transient, acute and chronic. Transient pain is brief and has a quick onset and offset, for example pain from an injection (Hawthorn & Redmond, 1999; Loeser & Melzack, 1999). Acute pain occurs in a temporal pattern due to the stimulation of nociceptors at a site of injury or damage (Hawthorn & Redmond, 1999; Loeser & Melzack, 1999). Medical intervention is often not required for acute pain as it often ceases when the underlying cause of the pain is treated (Hawthorn & Redmond, 1999; Loeser & Melzack, 1999). Chronic pain is long term and often requires medical attention (Loeser & Melzack, 1999). It may be related to damage within the nervous system as the body is unable to restore physiological function (Loeser &
Melzack, 1999). Up to a fifth of adults within Europe suffer from chronic pain with only 2% seeking help from a specialist (Hall, Morant, Carroll, Gabriel, & McQuay, 2013). Chronic pain often causes personality and lifestyle changes which affects quality of life (Hawthorn & Redmond, 1999). Breast pain is classed as a chronic pain condition in cases where pain is moderate to severe (approximately 15% of cases) and an intervention is often necessary as the symptoms can affect daily living and quality of life (QoL) (Blommers, De Lange-de Klerk, Kuik, Bezemer, & Meijer, 2002).

Pain can be detected within the nervous system by nociceptors, sensory nerve cells which transmit signals to the brain from the point of trauma or damage (Loeser & Melzack, 1999). Although most pain occurs from the stimulation of nociceptors, some forms of pain such as phantom limb pain, can be caused without the sensory path to the brain and spinal cord (Loeser & Melzack, 1999). Pathological pain is often in response to nerve damage which establishes an increased level of sensitisation to pain (Hawthorn & Redmond, 1999). This increase can; be a protective mechanism after injury, show the progression of disease (for example, arthritis pain increases with movement), and can cause pain in areas not necessarily subjected to trauma, such as internal organs (Hawthorn & Redmond, 1999).

The psychological and physical behaviours presented by pain sufferers vary, and it is suggested that this behaviour is often learnt (Loeser & Melzack, 1999). This is reinforced by Williams, Robinson and Geisser (1994) who suggested that a persons' beliefs about pain can affect; perception of pain, function and treatment efficacy or success. This is also reiterated by Hawthorn and Redmond (1999), who reported that pain expression or experience can be influenced by; adaptation, beliefs and attitudes, culture, personality, secondary gains and if a person has difficulties verbalising pain. The intensity of pain or the experience of pain is often determined by pain thresholds or tolerance levels. There are four typical thresholds; sensation threshold (lowest perception of sensation), pain perception threshold (initial and lowest feeling of pain), pain tolerance (highest pain threshold) and encouraged pain tolerance (highest pain threshold that can occur with encouragement from an external source) (Hawthorn & Redmond, 1999; Melzack & Wall, 1996).

Pain intensity is often worse when attention is placed on it or pain is anticipated, which suggests that distraction can help to reduce pain (Melzack & Wall, 1996) and this could be a suggestion why reassurance (that the breast pain is not cancer) is sufficient for up to 70.2% of women but is more effective for women experiencing mild pain (Barros, Mottola, Ruiz, Borges, & Pinotti, 1999). Studies in Ecological Momentary Assessment also suggest that context or situation is important when measuring behaviour or experience (Shiffman, Stone, & Hufford, 2008). This emphasises the importance of monitoring participants in their
home or usual settings rather than in the laboratory, as the recording of their pain experiences may be more accurate.

1.1.3 Breast pain prevalence

Prevalence is “The fact or condition of being prevalent, commonness” ("Oxford University Press," 2017). Recent research identified that breast pain affects up to 52% of the female general population in the UK (Scurr, Hedger, Morris, & Brown, 2014), although research suggests it is between 50 and 80% of women (Carmichael, 2008). Typically, it is classified as non-threatening or benign, yet reportedly the majority of patients attending breast clinics report with breast pain (Tavaf-Motamen, Ader, Browne, & Shriver, 1998) due to concerns that their breast pain is a sign of breast cancer (Clarkin et al., 2016; Sukanya, Nagarathna, & Sandhya, 2016). Breast pain is only a symptom of breast cancer in around 1% of cases (Carmichael, 2008). Cyclical breast pain is the most common type affecting between 45% and 60% of women in Britain and accounting for up to two thirds of cases at breast pain clinics (Ader & Shriver, 1998; Cairncross, 2010) with the other third attributed to non-cyclical and extra-mammary breast pain. It is interesting to note that whilst breast pain prevalence in Britain is similar to America (41% to 69%), Asian cultures have a much lower reported prevalence rate of around 5% (Ader & Browne, 1997; Rosolowich, Saettler, & Szuck, 2006), and a study conducted in Iran found 33% of females (not pregnant or breastfeeding, post-puberty and with no history of breast cancer and never had a mastectomy) had experienced some breast pain, with 11% having severe symptoms (Vaziri, Samsami, Rahimi, Rastgardoost, & Nick, 2016). Breast pain is therefore a condition within the UK which has the capacity to affect a large number of women, so it is important that the causes of breast pain are known and the treatments provided are appropriate. Movement-induced breast pain has been reported in up to 64% of marathon runners, indicating that breast pain is highly prevalent during exercise.

1.1.4 Breast pain aetiologies

The aetiology of breast pain is poorly understood, and it is suggested to have multiple causes and presents in different ways (Carmichael, 2008).

1.1.4.1 Cyclical breast pain

Changes to the breast that occur due to variations in hormone levels have been suggested as a cause of cyclical breast pain (Ader & Shriver, 1997). This is because this type of breast pain is directly related to the luteal phase of the menstrual cycle (Ader & Shriver, 1997). Pain generally occurs after ovulation (follicular phase) and prior to the onset of menstruation, however residual pain can be present during the whole menstrual cycle (Parsay, Olfati, & Nahidi, 2009). This link suggests a hormonally related aetiology; with
changes in levels of oestrogen and progesterone reported as a potential factor by a number of studies found within a meta-analysis (Smith, Pruthi, & Fitzpatrick, 2004). Women with cyclical breast pain often only gain relief with the onset of menopause (Ader & Browne, 1997; Barros, Mottola, Ruiz, Borges, & Pinotti, 1999; Mansel, 1994; Smith et al., 2004). Relief can also occur during other hormonally related events such as pregnancy (Smith, Pruthi, & Fitzpatrick, 2004), however, this has been disputed (Mansel, 1994; Smith et al., 2004). Vitae Agnus Castus has also been found to be an effective treatment for cyclical breast pain, possibly due to an effect on hyperprolactinemia (elevated levels of prolactin) and oestrogen receptors (Carmichael, 2008), also suggesting a hormonal aetiology. Consistent findings supporting the hormonal aetiology of breast pain have not been found (Rosolowich et al., 2006).

The level of fatty acids within the bloodstream can inhibit or exaggerate the influence of some hormones (Parsay et al., 2009). Consequently this been suggested as another potential cause of cyclical breast pain (Smith et al., 2004). The effectiveness of oils such as evening primrose oil (EPO) supports this (Mansel, 1994; Parsay et al., 2009). There are many theories relating to diet and fluid alterations but all have varying levels of backing (Smith et al. 2004). The breast swells during the menstrual cycle by up to 100 ml, however, there is no link between this increase in total body water and cyclical breast pain (Mansel, 1994; Milligan et al., 1975; Preece, Richards, Owen, & Hughes, 1975). This dispels fluid alterations as an aetiology of breast pain.

Fibrocystic changes of the breast have also been suggested as an aetiology of cyclical breast pain (Blichert-Toft, Nyboe Andersen, Henriksen, & Mygind, 1979; Smith et al., 2004). Yet, no consistent findings have been identified. Fibrocystic changes in women presenting with symptoms of cyclical breast pain are no different to those in women with non-cyclical breast pain or no history of breast pain (Morrow, 2000). However, fibrocystic changes are still being considered as a cause of cyclical breast pain as there is a suggested link between pain, tenderness and nodularity of the breasts (Smith et al., 2004).

A further suggested aetiology relates to psychological differences in women. Research has reported that women suffering from cyclical breast pain psychologically present themselves differently compared to those without breast pain; with increased anxiety, depression, somatisation and increased stress levels (Bahadir.Ozturk, Tugal, & Ozenli, 2015; Colegrave, Holcombe, & Salmon, 2001; Preece, Mansel, & Hughes, 1978). This indicates that this condition is often highly emotional for women and this can affect the care needed (Colegrave et al., 2001). Additionally, women who are more highly distressed are likely to seek further treatment due to anxiety and fearfulness (Colegrave et al., 2001). Furthermore,
it is often difficult for clinicians to identify whether the patient’s distress is causal or a consequence of their breast pain (Colegrave et al., 2001). Studies suggest a fear of cancer or sexual role conflicts are linked to cyclical breast pain, as well as being a potential sign of emotional abuse (Preece et al., 1978; Ramirez, Jarrett, Hamed, Smith, & Fentiman, 1995). Cyclical breast pain was also thought to be an expression of psychoneurosis (Preece et al., 1978). Preece et al. (1978) sought to disprove this theory as they found that women within their studies were psychologically stable and hypothesised that the underlying cause of breast pain was actually physiological. Whether these psychological differences are causal or consequential components of cyclical breast pain is unknown (Smith et al., 2004). The severity of these psychological differences, between symptomatic and asymptomatic women has been reported to decrease with treatment for cyclical breast pain (Rosolowich et al., 2006).

In summary, this section has identified that there are four suggested aetiologies of cyclical breast pain; hormonal, diet and fluid alterations, fibrocystic and psychological. There is a lack of conclusive evidence to determine the exact cause, although a link with the menstrual cycle seems to strongly suggest a hormonal cause.

1.1.4.2 Non-cyclical breast pain

There are many suggested aetiologies for non-cyclical breast pain. For example, pain resulting from; pregnancy, mastitis, trauma to the breast itself, thrombophlebitis, cysts, benign tumours, or cancer (Smith et al., 2004). It is also suggested that hormones may have an influence in non-cyclical breast pain as well as cyclical, with one study finding that the use of oestrogen or combined hormonal therapies resulted in breast pain for 16% and 32% of women respectively (Davies, Huster, Lu, Plouffe Jr., & Lakshmanan, 1999). Therefore, exposure to unnaturally occurring oestrogen may cause non-cyclical breast pain (Smith et al., 2004). An abstract within the European Journal of Surgical Oncology found that treating Vitamin D deficiency improved non-cyclical breast pain in 77% of patients (Li et al., 2014). However, further research investigating whether this is the case has found a greater incidence of vitamin D deficiency in women with breast pain, however, this was not statistically significant (Alipour et al., 2015). The study however did not define the types of breast pain or differentiate between breast pain and chest wall pain (Alipour et al., 2015). Therefore, the evidence is currently inconclusive whether this is true cause of breast pain. Additionally there is an association between duct ectasia and breast pain (Peters, Diemer, Mecks, & Behnkken, 2003; Smith et al., 2004). Research found that symptomatic women with both cyclical and non-cyclical breast pain typically have milk ducts of greater width than
asymptomatic women but those with non-cyclical breast pain have wider milk ducts on average than those with cyclical breast pain.

Non-cyclical breast pain is dissimilar to cyclical breast pain as often the pain experienced has an obvious aetiology. Despite this some non-cyclical breast pain has no identifiable aetiology or pattern (Smith, Pruthi, & Fitzpatrick, 2004). With a known aetiology, non-cyclical breast pain is easier to treat, for example, pain resulting from a cyst is treated by cyst drainage or removal. Other types of non-cyclical breast pain may not have an obvious treatment and may result in having to manage the pain experienced rather than stop it completely (for example pain resulting from pregnancy; this pain may only resolve once the woman has given birth).

1.1.4.3 Extra-mammary breast pain and other causes of breast pain

Extra-mammary pain typically presents itself as breast pain but is caused by underlying chest wall syndromes (Cairncross, 2010). These syndromes include; pleuritic chest pain, Tietze’s syndrome, chest wall trauma and occasionally Herpes Zoster (Cairncross, 2010; Smith et al., 2004). This type of pain is not actually a true breast pain therefore this type of pain once diagnosed can only be treated by treating the underlying condition. Treatments used for cyclical and non-cyclical breast pain will not have the same effect on extra-mammary breast pain. Fibromyalgia has also been suggested as a different diagnosis of breast pain (Smith et al., 2004). Research has identified a relationship between breast pain and fibromyalgia which suggests they have similar underlying causes or pathology (Sen, Kilic, Cemeroglu, & Icen, 2015). It is therefore important for women who experience breast pain to have the type of pain identified to ensure the correct treatment is used.

1.1.4.4 Movement-induced breast pain

Breast pain can also be caused by excessive movement of the breasts. The breast moves in three directions when running; anterioposteriorly, mediolaterally, and vertically in a figure of eight pattern (Scurr, White, & Hedger, 2009). Breast movement (displacement, velocity and acceleration) in these three directions has been correlated with breast pain (Scurr, White, & Hedger, 2010). Displacement is used widely within the literature to describe breast motion. The definition of the word displacement is “The action of moving something from its place or position” (“Oxford University Press,” 2017). In the literature this type of breast movement should be described as range of motion (ROM) as the breast returns to its original position and there is no change in the place and position of the breast. Consequently, this movement will be referred to as ROM in this thesis. Therefore as the magnitude of breast ROM decreases, breast pain also decreases (Milligan, Mills, Corbett, & Scurr, 2015; Scurr, White, & Hedger, 2010). Interestingly, research into two-step star
jumping found breast pain was negatively correlated with breast acceleration (Bridgman, Scurr, White, Hedger, & Galbraith, 2010) although these variables were correlated in Scurr, White and Hedger (2010) however is it recognised that these activities differ in intensity. Literature suggests however, that it is vertical ROM that is more closely associated with breast pain (Bridgman et al., 2010; Mason, Page, & Fallon, 1999; Scurr et al., 2010).

Another study investigating breast asymmetry, found a strong correlation between anteroposterior ROM and breast pain for the dominant breast (breast with the greatest ROM), however for the non-dominant breast mediolateral ROM had the strongest relationship (Mills, Risius, & Scurr, 2014). It is therefore important when assessing movement-induced breast pain that ROM, velocity and acceleration are all assessed in all directions. Breast movement also increases with breast size (McGhee, Steele, Zealey, & Takacs, 2013).

Within breast biomechanics literature, the terms breast pain and breast discomfort have been used interchangeably. Discomfort is defined as “slight pain” (“Oxford University Press,” 2017) and the descriptive term discomforting is used to measure pain within the Present Pain Intensity scale within the McGill Pain Questionnaire and the Breast Pain Questionnaire (Khan & Apkarian, 2002b; Melzack, 1987). This thesis will use the term ‘breast pain’ and not ‘breast discomfort’ throughout to describe pain experienced in the breast.

A time lag between breast and body movement has also been associated with movement-induced breast pain (Haake & Scurr, 2011; Scurr et al., 2009). The time lag is attributed to the elastic and inertial properties of the breast (Scurr et al., 2009) and the association with breast pain was linked to an increased acceleratory load on the weak internal supporting structures of the breasts (Scurr et al., 2009). The net force generated at the lowest point of vertical breast ROM (when the breast may make contact with the anterior thorax) has also been linked with breast pain (McGhee et al., 2013). Increasing the levels of breast support not only limits breast movement but also the associated forces which contribute to movement-induced breast pain (McGhee et al., 2013). Breast biomechanics research promotes wearing a bra with high levels of support to reduce breast movement during exercise, consequently minimising breast pain (Bridgman et al., 2010; Scurr et al., 2010).

Tension on the internal supporting structures has also been speculated to be a factor causing movement-induced breast pain (Mason et al., 1999). Haake, Milligan and Scurr (2012) investigated whether strain and acceleration could predict movement-induced breast pain during running. Peak dynamic strain and maximum acceleration could also contribute to breast pain (Haake et al., 2012).
1.1.4.5 Other considerations

1.1.5 Breast pain and quality of life

Breast pain is negatively associated with QoL (Carmichael, Bashayan, & Nightingale, 2006; Scurr et al., 2014). This is not unusual, as across pain studies, QoL seems to be negatively affected. Although pain is not completely synonymous with QoL, treating pain often has a positive effect (Niv & Kreitler, 2001). The studies that have used bras to treat breast pain (Hadi, 2000; Wilson & Sellwood, 1976; Woollett, Insley, Bailey, & Williams-Jones, 2012), did not investigate whether the reductions in breast pain also improved the QoL of their participants. This is an important secondary outcome which, as of yet, has not been investigated.

1.1.6 Bras as a treatment for breast pain

Within the literature it is frequently recommended that ‘a well-fitting and supportive bra’ will help reduce symptoms of breast pain (Cairncross, 2010; “Cyclical breast pain - Treatment,” 2012; Pearlman & Griffin, 2010; Rosolowich et al., 2006; Wilson & Sellwood, 1976). Movement-induced breast pain (during walking, aerobics, jogging and running) can be reduced by supporting the breasts in a bra (Mason et al., 1999; Scurr et al., 2010). “Support” is typically defined in the literature as breast movement reduction, with bras that have increased levels of movement reduction classed as ‘high support’ (Mason et al., 1999; Scurr, White, & Hedger, 2011).

Research has determined that as the level of support provided by a bra increases, the intensity of breast pain decreases, due to a reduction in ROM, velocity and acceleration of the breast tissue (Mason et al., 1999; Scurr et al., 2010). It is also hypothesised that a poorly fitting bra is associated with breast pain (McGhee & Steele, 2010b) as the components of the bra can dig into the breast tissue.

Three studies (Hadi, 2000; Wilson & Sellwood, 1976; Woollett et al., 2012) have assessed the effectiveness of bras at reducing breast pain with up to 85% relief of symptoms (Hadi, 2000). These studies are not without limitations. The lingerie market and bras have changed significantly since the 1970’s when the first study was completed and showed effectiveness (Wilson & Sellwood, 1976) (26% complete relief, 49% improved symptoms, 21% no improvement and 9% worsened). Additional to this, Hadi (2000) compared the effectiveness of a sports bra to a typical pharmacological treatment for breast pain, the sports bra was more effective (85%) at reducing breast pain than Danazol (58%), and patients on Danazol had a high relapse of their breast pain when Danazol was stopped (42%). Regardless of
their benefits, the use of sports bras is low in the UK general population (32% during physical activity (Brown, Burnett, & Scurr, 2015)), and therefore it could be suggested that many women would not choose to wear a sports bra to relieve their breast pain, or they may not be aware of the benefits. In both studies (Hadi, 2000; Wilson & Sellwood, 1976), one bra style was provided to participants. Previous research conducted on women with larger breasts has indicated that due to the large range of breast masses and volumes, one bra design may not be suitable for all, as the bras may not be able to provide the same level of support (McGhee et al., 2013). This identifies a need to investigate the appropriateness of bras on an individual basis. This thesis therefore should start by identifying the bra preferences and concerns of women with larger breasts who experience breast pain, to ensure the bras chosen meet the needs of the cohort.

The approach by Woollett et al. (2012) allowed patients (n = 100) to purchase their own bras following a bra fit combined with a 28-day course of analgesia. As a result, 41 out of 91 patients reported the improvement in breast pain to be a result of the new bra and the medication and 26 attributed the improvements to their change in bra size alone. Despite a high number attributing their reduction in pain to the bra or the bra and medication combined, it is difficult to conclude which had the greatest influence on breast pain. Additionally, 39 patients struggled to find an appropriately fitting bra on their own. It is therefore important that women have some guidance to find an appropriate bra.

Despite these studies (Hadi, 2000; Wilson & Sellwood, 1976; Woollett et al., 2012) demonstrating the effectiveness of the bra as a treatment for breast pain, there has yet to be a Randomised Controlled Trial (RCT) to evaluate the effectiveness of the bra as a method of reducing breast pain. This is necessary for clinicians to make an evidence-based recommendation for bras as a treatment for breast pain. Despite the lack of a RCT, the literature already recommends wearing a well-fitting bra as a method of managing breast pain (Cairncross, 2010; Harrison & Halliday, 2010; Rosolowich et al., 2006; Vaidyanathan, Barnard, & Elnicki, 2002). By completing an RCT, it will allow for recommendations to be made with the knowledge that this method of treatment has undergone the same rigorous practices as a drug trial.

1.1.7 Breast size

Although there is no literature to suggest that women with larger breasts experience breast pain more than women with smaller breasts (cyclical, non-cyclical or extra-mammary). There is rationale to investigate the effectiveness of bras for women with larger breasts who experience breast pain. Women with larger breasts have historically had greater difficulty in purchasing bras (Greenbaum, Heslop, Morris, & Dunn, 2003). This is due to fitting issues
Introduction

because of the size and shape of their breasts (Greenbaum et al., 2003). Additionally, the traditional method of bra fitting, using an under-bust and over-bust tape measurement (Greenbaum et al., 2003; Zheng, Yu, & Fan, 2007), was initially designed for bra cup sizes D and below (Greenbaum et al., 2003), demonstrating that this method does not apply for women who have bra cup sizes above a D cup. Additionally, the traditional method is inaccurate by up to four cups sizes in women with larger breasts (White & Scurr, 2012). Niddam et al. (2014) also reports that the differences in bra sizing across countries and bra companies are confusing for patients and the practitioners. The difficulties associated with finding an appropriately fitting bra for women with larger breasts, suggests that this population of women may have a greater need for an appropriately prescribed bra to reduce breast pain as recommended in section 1.4.6.

1.1.8 Trial Designs

When developing an intervention; efficacy and effectiveness trials have to be considered to assess the worth of the trial (Flay & Phil, 1986). Flay and Phil (1986) and Victora, Habicht, and Bryce (2004) report that an efficacy trial assesses whether an intervention does more good than harm under optimum or ideal conditions whereas an effectiveness trial does the same but under real world conditions. The RCT is considered the gold standard trial design for efficacy trials (Faraoni & Schaefer, 2016; Kaptchuk, 2001; Levati et al., 2016). An RCT reduces the systematic error and bias that is associated with an intervention, making an RCT more comparable to other trials and the results will not be hindered by the error or bias (Brewin & Bradley, 1989). An RCT typically involves a treatment and control (or a placebo) group, where participants are randomised into one of the two groups (Flay & Phil, 1986). Additionally, RCT’s typically have a specific cohort involved in the trial and a standard procedure for the delivery of the intervention (Flay & Phil, 1986). The randomisation aspect of an RCT is designed to make all factors across the intervention and the control group equal. This includes factors such as age, and in this case, breast pain.

Evaluation is an important component for any intervention trial, Levati et al. (2016) presents a number of processes that have previously been used to evaluate interventions. These include the Medical Research Council’s (MRC) 2000 and 2008 criteria, the multiphase optimisation strategy (MOST), the normalisation process theory (NPT) and the process modelling in implementation research (PRIME). Each of these evaluations follow the same four overall categories; development, piloting, evaluation and implementation. Seventeen of the 27 trials (62%) reviewed by Levati et al. (2016) used either the MRC 2000 or 2008 framework to evaluate their trials.
The Medical Research Council’s (MRC) guidelines for developing complex interventions have been chosen for use within this thesis (Craig, Dieppe, Macintyre, Michie, et al., 2008). Complex interventions are different to simple interventions as they have multiple interacting components (Craig, Dieppe, Macintyre, Michie, et al., 2008). There are four phases for developing an intervention using these guidelines (Craig, Dieppe, Macintyre, Mitchie, et al., 2008): development, piloting/feasibility, evaluation and implementation (Figure 1.1). This process is often cyclical (Craig, Dieppe, Macintyre, Michie, et al., 2008) but can be linear or these phases may be completed in any order.

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**Figure 1.1:** Medical Research Council 2008 guidelines for developing an complex intervention.

Establishing an intervention that is effective at managing breast pain and improving QoL for women with larger breasts, presents an opportunity for a wider scale management pathway, which could be implemented in any clinic for symptomatic patients. This will allow clinicians have a referral route for patients to obtain bra recommendations based on an evidence-based bra prescription.

1.1.9 Research philosophy

Ontology is the philosophy of reality, which is inherently linked with epistemology, the philosophy of knowledge as it demonstrates the how we know the reality.
(Krauss, 2005). Additionally, methodology, also linked to epistemology as it is based around the practices associated with gaining knowledge (Krauss, 2005).

The research in this thesis, is focusing on a relativistic constructivist ontology. Relativism is defined as “the belief that truth and right and wrong can only be judged in relation to other things and nothing can be true or right in all situations” (Cambridge Dictionary, 2018b) and constructivism is “a theory that learning is an active process and that people gain knowledge and understanding through the combination of experiences and ideas” (Cambridge Dictionary, 2018a).

This perspective is where multiple realities exist, which have been constructed by the cohort with a similar condition or phenomena of interest (Krauss, 2005). For example, in this thesis, the patients with breast pain are the focus of this intervention. This specific group may have particular feelings or considerations, that other groups do not share, yet the results of this thesis will relate to the patient’s own truth. A key factor in constructivist research is that data is acquired through interaction with subjects (the patients with breast pain) (Krauss, 2005). In breast pain research this is an appropriate approach, as patients must feel an improvement in their condition, to feel satisfied with their treatment or intervention. As a result of feeling an improvement in their breast pain, these patients are less likely to return to the clinic for further advice, minimising the re-referrals to the clinic and reducing a burden on the NHS.

1.1.10 Summary

To summarise breast pain is a prevalent condition in the UK affecting around 52% of females (Scurr et al., 2014). Breast pain is poorly understood and there are a number of different aetiologies which have been presented in the literature. Breast pain also negatively affects QoL (Carmichael et al., 2006). Bras have previously been effective at treating breast pain, yet no RCT has been conducted to assess this effectiveness (Hadi, 2000; Wilson & Sellwood, 1976). This is despite the RCT is the gold standard method for trials as it reduces the effect of systematic error (Brewin & Bradley, 1989)

A bra fit is not enough to ensure women have the right bras, previous research has identified that women, when provided with a bra fit, find it difficult to purchase bras without assistance (Woollett et al., 2012). Additionally, research has found that one bra may not be suitable for all women with larger breasts due to the variations in breast mass and volume (McGhee et al., 2013). Therefore women with larger breasts are most likely to benefit from a bra
intervention. This is also due to the size and shape of their breasts, but also due to the traditional method of bra fitting being inaccurate (Greenbaum et al., 2003; White & Scrr, 2012).

The MRC 2008 Guidelines will be used to develop the bra intervention for this thesis. These guidelines have four phases; development, feasibility and piloting, evaluation and implementation (Craig, Dieppe, Macintyre, Mitchie, et al., 2008)

1.2 **Rationale**

The breasts internal supporting structures are the Cooper’s Ligaments (Gefen & Dilmoney, 2007) and externally is supported by skin (Page & Steele, 1999). These supporting structures are weak, and therefore external support from a bra is often recommended (Bowles et al., 2008). Breast pain is a highly prevalent condition which affects around 52% of the UK female population (Scurr et al., 2014) however it is poorly understood. Pain itself is complex, with three main types; transient, acute and chronic. When breast pain intensity is severe enough, it may warrant intervention as it can affect daily living and reduce quality of life (QoL) (Blommers et al., 2002). This type of breast pain warrants intervention as it can affect daily living and reduce quality of life (QoL) (Blommers et al., 2002). Although most breast pain is benign, large numbers of women are attending breast clinics with this condition (Tavaf-Motamen et al., 1998). This thesis should therefore investigate the effect of the bra intervention on breast pain and QoL.

Research has identified that bras are effective at reducing breast pain, and as a consequence, they are recommended as a treatment for breast pain (Cairncross, 2010; Hadi, 2000; Rosolowich et al., 2006; Wilson & Sellwood, 1976). Despite this recommendation, there has been no randomised controlled trial (RCT) conducted to confirm the findings of previous research. Research has identified that one bra style may not be appropriate for all women due to the differences in breast volume and masses (McGhee et al., 2013), therefore previous research which has prescribed one bra style to all participants may not be as effective as prescribing bras on an individual basis. Therefore, the bra intervention should be a RCT which offers different bras to each patient on an individual basis.

Women with larger breasts are most likely to be wearing incorrectly fitting bras due to the size and shape of their breasts (Greenbaum et al., 2003). Therefore, women with larger breasts who are experiencing breast pain are most likely to benefit from having a bra prescribed to treat their breast pain. The patients in this study should therefore have larger breasts.
1.3 Thesis aim

The overall aim of this thesis was to develop, pilot and evaluate a bra intervention for women with larger breasts who are experiencing breast pain, with the aim of improving breast pain and QoL.

1.4 Thesis outline

This thesis will follow the MRC 2008 guidance (Craig, Dieppe, Macintyre, Michie, et al., 2008) to develop, pilot and evaluate an intervention for prescribing bras to women with larger breasts who experience breast pain (Figure 1.2). The first step of the development phase is to identify the existing evidence for the intervention. The literature within section 1.1 demonstrates that the bra has been shown to reduce breast pain and improve quality of life in women (Hadi, 2000; Wilson & Sellwood, 1976; Woollett et al., 2012). Women with larger breasts typically find the process of finding appropriate breast support difficult due to the size and shape of their breasts (Greenbaum et al., 2003). Therefore, it has been assumed that this group could benefit more than women with smaller breasts from a bra intervention if they are experiencing breast pain. The intervention itself will be formed of a bra prescription, where women will be individually prescribed an appropriate bra for them, as previous research has either assigned one bra style to all participants (Hadi, 2000; Wilson & Sellwood, 1976), or allowed self-selection of bras (Woollett et al., 2012). The prescription will allow for individual needs and preferences to be a priority.

Figure 1.2: The outline of this thesis and how it links with the stages presented in the MRC guidelines for developing complex interventions (Craig, Dieppe, Macintyre, Mitchie, et al., 2008)
The next step within this thesis is the development of the intervention (Chapters Two to Five). For the intervention to be piloted, a number of factors need determining:

- The current bra preferences and concerns of women with larger breasts who experience breast pain (to identify the specific bra needs of this cohort).
- The bras to be assessed within the intervention (to have a range of bras for the patients to be assessed in). These bras will form the treatment itself for the group who have the bra prescribed to them within the RCT.
- Following this, the method of prescribing the bra and the methods of measuring the outcome of the RCT should be determined.

Once these have been determined, a feasibility/pilot of the RCT will be conducted and the RCT will be evaluated to demonstrate whether the intervention is effective and to communicate the next steps taken (Chapter Six) (Craig, Dieppe, Macintyre, Mitchie, et al., 2008). The aim will then be to implement the intervention if positive outcomes are achieved or further develop the intervention.
2 Chapter Two: The bra preferences and concerns experienced by women with larger breasts who are experiencing breast pain.

2.1 Introduction

Understanding the bra preferences and concerns of women with larger breasts who experience breast pain is important as it ensures the bras chosen for use within the bra intervention were appropriate for the needs of the cohort. It will also increase the likelihood of patients adhering to wearing the bras during the intervention. Research has previously reported the bra preferences of an ageing female population, with bra comfort being the top preference (Risius, Thelwell, Wagstaff, & Scurr, 2014). Other studies have suggested what women want from their bras and the role of the bra itself (Hart & Dewsnap, 2001; Sukumar, 2007; Tsaousi & Brewis, 2013; Tsarenko & Strizhakova, 2015). Additionally, anecdotally women have reported sacrificing comfort for beauty (Odebiyi et al., 2015). Yet despite some research into bra preferences, there has been no investigation into the bra preferences of women who experience breast pain. As breast pain is a condition which is not experienced by all women, the preferences and concerns of this population may be different to asymptomatic females, which could be an obstacle in finding an appropriate bra. With breast size increasing (Brown & Scurr, 2016), it is also important to understand the bra preferences and concerns of women with larger breasts.

There are many types and styles of bras available on the market, and therefore it could be difficult to determine which styles may be suitable for symptomatic women. There is a large range of bra sizes now available, for example a UK retailer with a store on most city high streets (Debenhams) currently advertise 157 bra sizes (excluding bras advertised in S/M/L or dress sizes), making bra fit an important consideration. Additionally, bras in some retailers, such as Marks and Spencer®, have ranges specifically for larger cup sizes (DD+). The styling of the bras for a larger cup sized women often differs to the smaller sized bras, making the variation in bras even greater. It is therefore important that the bra preferences and concerns of women with larger breasts are assessed to ensure the bras chosen are representative of the current bra availability on the market.

Research has determined that an increase in breast support in the form of a sports bra can help to relieve movement-induced breast pain (Mason et al., 1999; Scurr et al., 2010). When sports bras are tested to investigate their ability to reduce breast movement and associated breast pain, they are often examined during sporting activities (Bridgman et al., 2010; Mason et al., 1999; Risius, Milligan, Mills, & Scurr, 2014; Scurr et al., 2009, 2010; Scurr, White, & Hedger, 2011). Reducing physical activity levels is mentioned as one of the methods to reduce breast pain by women (Burnett, White, & Scurr, 2015) but is not
recommended due to other health implications. Despite reducing levels of physical activity, many activities of daily living and occupational activities may still need to be undertaken. Some of these activities (for example, manual work relating to a particular job or housework and gardening) (Powell & Myers, 1995) may be vigorous enough to initiate movement-induced breast pain. The activities that typically cause movement-induced or increase cyclical or non-cyclical breast pain are the ones that should be focussed on. This will determine whether the bras provide appropriate breast support, and will hopefully reduce the breast pain associated with these activities.

Bra preferences and concerns of women with larger breasts who are experiencing breast pain, should be investigated via a qualitative study because qualitative methods allow for the understanding of attitudes, exploring knowledge and experiences (Kitzinger, 1995; Robinson, 1999).

There are three methods typically used to collect such qualitative data. These are questionnaires, focus groups and interviews. Questionnaires are typically used to collect a large quantity of data but often the quality is reduced due to the question type and space provided for answers (Morgan, 1996). Focus groups and interviews can be conducted in a structured or semi-structured manner to enhance the quality of discussions and increase the chances of discovering more common themes compared to questionnaires (Morgan, 1996; Powell & Single, 1996). The benefit of using a focus group over an interview is the multiple participants, the group dynamics and agreement and debate between participants can enhance the quality of data obtained, compared to an individual interview situation (Wilkinson, 1998). It is suggested that a combination of the focus group and interview scenarios are optimal, as interviews can supplement the underlying constructs obtained from the focus groups (Jones, 2002; Lambert & Loiselle, 2008). Fewer focus groups and interviews are often conducted compared to the quantity of data that can be obtained by questionnaires and the number of these conducted often relate to the point that data saturation occurs (Guest, Bunce, & Johnson, 2006). Guest et al. (2006) investigated data saturation, and identified that 92% of codes were identified when seven to 12 transcripts were analysed, with 73% occurring after the first six transcripts. Therefore, it could be suggested that this is a minimum number (n = 6) of focus groups and interviews required for data saturation.

To summarise, the bra preferences and concerns for women with larger breasts who are experiencing breast pain are unknown, but understanding this may help in prescribing and assessing bras and consequently this will help to ensure patients adhere to wearing them. In addition, it is known that typical bra fitting methods do not cater for larger bra sizes due
to the size and shape of the breasts (Greenbaum et al., 2003; White & Scurr, 2012), therefore these women are more likely to be incorrectly bra fitted. Focus groups and interviews will allow rich information to be collected along with bra problems, whether women perceive a benefit in a bra prescription for breast pain, and activities that induce breast pain.

2.2 Aims

The aims of this chapter were to:

1. Establish the bra preferences and concerns experienced by women with larger breasts who are experiencing breast pain
2. To investigate the perceived benefits of a bra prescription service for women with larger breasts who are experiencing breast pain
3. To investigate daily activities that increase breast pain for women with larger breasts who are experiencing breast pain

2.3 Methods

2.3.1 Participants

Following institutional ethical approval, 10 female participants who were a UK D and above bra cup size were recruited for this study. Participants self-reported their breast pain as occurring each month and that they experienced breast pain in the two months prior to the focus groups and interviews. Participants were excluded if they were currently pregnant, had been pregnant or had breast fed within the past year. Participants were also excluded if they; had any surgery to the breasts, were peri- or post-menopausal or under the age of 18 years. The average age of participants was 30 ± 10 years. Self-reported UK bra sizes ranged from 28 to 42 under band and D to JJ cup sizes. Three participants were using contraceptive medications (contraceptive pill = 2, coil = 1) and two participants had given birth. Both participants who had given birth stated they did not experience breast pain prior to childbirth.

Participants were recruited using advertisement; within the University of Portsmouth, in local gyms, on social media and via women who had previously expressed an interest in participating in breast health studies at the University of Portsmouth. Additional participants were obtained as a result of media coverage from a recently published paper (Burnett et al., 2015). Despite wide coverage of the study advertisements and multiple recruitment drives, participant recruitment was lower than anticipated, but fell in the range for data saturation (Guest et al., 2006). Participants either took part in one focus group (n = 4), individual face-to-face interviews (n = 3) or telephone interviews (n = 3), resulting in seven transcripts. Participants received information sheets prior to participation and informed
consent was obtained. Participants were then given unique participant numbers to maintain confidentiality and anonymity.

**2.3.2 Procedures**

Participants completed a survey (Appendix A) at either the beginning of the interview (focus group and face-to-face interviews) or online prior to the telephone interview. The survey was completed to understand the demographics of the participants, their typical levels of breast pain, and treatments used. The survey was developed from previous breast health surveys and the Short-form McGill Pain Questionnaire (Burnett et al., 2015; Khan & Apkarian, 2002b; Melzack, 1983). Participants were given a verbal briefing about the topics, confidentiality and anonymity and were made aware that their opinion that was sought. Due to it being a group conversation, participants within the focus group were asked to maintain confidentiality about the other participants and the topics discussed within the session. The time allotted to the focus group was 120 minutes (for briefing, survey completion and discussion) (Kitzinger, 1995; Powell & Single, 1996), with 60 minutes for each of the individual interviews. Focus groups and interviews were conducted between June and August 2014. Focus groups and individual interviews were audio (UltraDisk Dvr7, Digital Voice Recorder) and video (Panasonic SDR-H85, Panasonic, Japan) recorded (to interpret body language), and telephone interviews were audio recorded only. Participants were made aware of the recordings during initial contact, within the information sheets and prior to the start of the discussions.

Participants within the focus group were sat in a circle to promote interaction, discussion and debate (Powell & Single, 1996). Focus groups and interviews were semi-structured using an initial list of 13 questions on the topics of bras, bra fitting and breast pain (Appendix B). Questions started broad, focusing on bra styles (what styles of bras do you typically wear?), to generate a discussion and became more focused about bras and breast pain as the discussion moved on. For example, asking participants whether they wore different bras when experiencing breast pain and whether bras made their breast pain worse or better. Conversational probes were used throughout the discussions to enhance the volume and quality of data obtained (such as asking why they answered in the way that they did), as well as to ensure all participants within the focus group were contributing to the discussion (Krueger, 1998; Powell & Single, 1996; Tiggemann, Gardiner, & Slater, 2000). The researcher attempted to show empathy towards the subjects and their feelings during the focus group which was important for identifying the participants intended meanings during the discussion (Krauss, 2005). Focus groups and interviews were conducted in a secure locked room with only the researcher and participants present.
2.3.3 Data Analysis

2.3.3.1 Breast Pain Survey

Questions which resulted in a numerical answer were not coded but left in their original state (for example, age). For the questions relating to the participants worst day of pain and the number of days of breast pain they experience per month; if participants gave a range, for example “10 to 12 days” instead of “10 days” their answer was excluded from the analysis. Categorical questions (yes/no) were coded as yes = 1 and no = 2, the Present Pain Index (PPI) (Melzack, 1975) was coded mild = 1, discomforting = 2, distressing = 3, horrible = 4, excruciating = 5. The sensory descriptors for pain were coded based on the scaling determined within Melzack and Torgerson (1971). The coding for whether breast pain occurred in one or both breasts was; left breast = 1, right breast = 2 and both breasts = 3. The number of years of breast pain was coded; less than one year = 1, one to two years = 2, two to three years = 3, three to four years = 4, four to five years = 5, more than five years = 6. Bra size was not coded but split into the under band and cup sizes for analysis. The remaining questions within the survey resulted in open-ended answers and therefore no coding was completed. Descriptive data analyses were then conducted where data were reported as frequencies (treatments for breast pain), means (breast pain intensity) and modes (description of breast pain, duration of breast pain and laterality of breast pain).

2.3.3.2 Focus Groups and Interviews

Audio data were transcribed by the researcher (Microsoft Word, 2010) who conducted the focus groups and interviews, resulting in 174 pages of single spaced text. Video data for the focus groups and face to face interviews were referred to throughout to establish which participant was speaking (focus groups) and whether there were any indications from non-speaking participants on agreement or disagreement (focus groups). Video data were also used to determine body language that was demonstrated by participants within both the focus group and interviews. Data were transcribed using participant numbers only and any of the participants names that were mentioned within the discussions were replaced with participant numbers.

Full transcripts were condensed by removing occasions where the researcher was expressing their understanding, for example, within the middle of conversation with a participant if the researcher said ‘yes’ or ‘sure’ as this separated conversational blocks of text into shorter sections. This was to improve the flow of the transcript so upon analysis blocks of continual conversation were presented. No data were removed that related to the study topics or conversational discussion completed by the participants.
Condensed transcripts were then imported to QSR NVivo 10 Qualitative Analysis software. Inductive content analysis was completed within NVivo by the researcher who conducted the focus groups and interviews. Transcripts were analysed and coded in order of completion (focus group, face to face interviews then telephone interviews) which meant the analysis was both deductive and inductive following the focus group analysis (Schulze & Angermeyer, 2003). Relevant blocks of text were identified and coded within initial analysis of each transcript and coded accordingly (Schulze & Angermeyer, 2003). Codes were developed to reflect the attitude of the state (positive or negative) and were revised throughout the analysis (Schulze & Angermeyer, 2003). Codes were then grouped into higher-order themes and then general dimensions.

Following first analysis by the researcher data were triangulated by a secondary researcher with experience in the area of breast health and in triangulation. Some codes were revised (to make their meaning clearer) by the initial researcher following discussions about the coding structure and interpretation of findings (Coggan, Patterson, & Fill, 1997; Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999; Schulze & Angermeyer, 2003). The frequency of reported codes is presented throughout the results section of this chapter. A frequency analysis was then conducted to determine whether participants would wear a sports bra on a daily basis to understand if the participants could be prescribe sports bras over everyday bras.

Following the triangulation, participants were given a short report which detailed the overall findings. This was to ensure the interpretation of the discussion was reported correctly. This relates to the researchers constructivist approach to analysis as interpretation of the results is important to ensure the appropriate meaning of the discussion is reported (Krauss, 2005). Reports were anonymous and did not contain any direct quotes. Participants were asked to provide any feedback on the report, whether they agreed with the overall findings, and to provide any additional comments they wished to make (Coggan et al., 1997). Of the 10 participants who were sent the participant report, only one participant responded with feedback. Feedback was positive and the participant was in agreement with the overall findings for this study.

2.4 Results

2.4.1 Descriptive data

The results from the survey showed that the mean intensity of breast pain for participants was 5.8 (SD = 1.8) out of 10, with participants describing breast pain as ‘discomforting’ (mode). The number of days participants experienced breast pain ranged from two days to 28 days per month, with most participants (n = 6) reporting that pain had been present for
more than five years. For nine out of 10 participants breast pain was bilateral and mostly affected the lower half of the breast. The most frequently reported descriptors of pain were ‘pulsing’, ‘heavy’ and ‘tender’.

The reported treatments currently or previously used by participants included; ‘pain relief medication’ (n = 5), ‘gentle massage’ (n = 3), ‘evening primrose oil’ (n = 3), ‘relaxation techniques’ (n = 3), ‘changing breast support’ (n = 3), ‘changing contraceptive medication’ (n = 2), ‘altering diet/fluid intake’ (n = 2), ‘non-steroidal anti-inflammatory drugs’ (n = 2), ‘gentle exercise’ (n = 2), ‘starflower oil’ (n = 2), ‘heat/cold application’ (n = 1). Three participants noted side effects to treatments, one participant stated positive side effects (e.g. pain reducing with changing breast support, starflower and evening primrose oil and pain relief medication), whereas the remaining two participants noted negative side effects relating to the contraceptive pill, these included changes in breast size, increased heaviness of the breasts and an increase in breast pain, in addition to other hormonal side effects such as mood swings, anxiety and sweating. Three out of 10 participants had not tried any treatments for their breast pain.

2.4.2 Bra Preferences and Concerns

A total of 176 raw data themes were established with 33 higher order themes established within seven general dimensions of; comfort, support, practicalities, aesthetics, fit, purchasing factors and fabric. Frequency analysis showed comfort was the most frequently mentioned dimension (Σ = 77) and accounted for 20% of the total number of mentions within the transcripts. This was followed by support (Σ = 69, 18%), practicalities (Σ = 61, 16%), aesthetics (Σ = 56, 15%), fit (Σ = 56, 15%), purchasing factors (Σ = 50, 13%) and fabric (Σ = 14, 4%). Verbatim quotes have been extracted from the transcripts to emphasise the key findings within the general dimensions.

2.4.2.1 Comfort

The general dimension of comfort (Figure 2.1) resulted in four higher-order themes emerging from the focus groups and interviews; bra components, dislike of bra tightness, softer fabrics and general comfort. The most reported raw data theme relating to bra components was associated to underwire;

“I prefer wires absolutely, I never look at non underwired bras but…if you’re not wearing the right size they can be very problematic, they can really dig into you…”

The two most reported raw data themes to emerge relating to bra tightness were firstly that having some space within the bra was good, making the bras more comfortable. Bras were also reported to feel uncomfortable when they were tight;
“I don’t think underwiring makes the pain worse I think I am already irritated with the pain that I can’t deal with underwiring…and feeling tight around anywhere else when my breasts are in pain I think that’s more of the issue”

Figure 2.1: General dimension of comfort relating to bra preferences and concerns reported by women with larger breasts and breast pain (numbers in brackets are number of times this raw data theme was reported)

2.4.2.2 Support

The general dimension of support resulted in seven higher-order themes (Figure 2.2). A lack of natural support was an important factor for participants who stated their pain increased as their breasts provided poor natural support;

“like the size I am and the fact that it’s natural means that when I take the bra off gravity takes over so when they’re [breasts] in pain and I take it [bra] off…they [breasts] just feel really heavy…And there’s just pain shooting out like down the side and around underneath”

Despite bra tightness being seen as a negative factor (Figure 2.1), compressive support was mentioned to help breast pain. In addition participants indicated wearing smaller bra sizes to obtain compression to feel adequately supported during daily living.
Practicalities

The third most frequently reported general dimension was practicalities (Figure 2.3), accounting for 61 of the total reported mentions. There was a dislike of being able to see the bra under clothes, in the appearance under clothing higher order theme, and that smoothness was a preferred look despite being attracted to lacy bras. One participant mentioned that the lace could sometimes poke through clothing and it would make her feel conscious that people looking at her would think the lace was her nipples that could be seen through the clothing.

The lack of available bra sizes was the second highest higher-order theme developed from the data, within the practicalities theme, with the most reported raw data theme being that pretty bras are difficult to find in larger sizes. The quotation below demonstrates this with an emphasis on how the lack of sizes makes them feel when bra shopping;

"I live just next to Wonderbra so whenever I go to work or from work I just pass by it and they’ve got amazing bras, amazing colours and everything and I go in and ‘no we don’t go up to an E cup, no sorry’"
2: I have had to stop going into the fancy bra shops because it makes me sad...I go in there and think look at all these...oh no, not even close [reference to lack of bra sizes]"

2.4.2.4 Aesthetics

The general dimension of aesthetics accounted for 56 of the reported mentions. A total of five higher order themes were present within this dimension (Figure 2.4). Participants within the focus group expressed a liking for their breasts to look separate;

"1:...but it's like if they [bras] go all the way up it just looks like there is one boob sort of thing, because they are like so close to each other and it looks really, really awful and like with the Wonderbra ones it kind of keeps a bit of space here [pointing between breasts] and makes that sort of cleavage look, like normal, yeah...

2: that why I can't wear the um, unwired ones because it all just smushes together to one uber-boob which is not nice

3: [laughs] uber-boob, love it!...yeah I like the natural look where you have two separate"

The full cup bra was discussed positively, but also in a negative light with comments of the
full cup bra shape making participants feel ‘less confident’, ‘not sexy’ and ‘old’. All participants that took part in this study experienced breast pain but despite this, one participant would choose style/aesthetics over relieving her breast pain;

“but I think it is to do with confidence as well because for example I would never go for as you called the full cup bra…it makes them look like two pyramids and even if it would be the most comfortable thing in the world, I still wouldn’t wear it because I would feel rubbish in it…I would be conscious about the way it would look…so I would rather have a balance of maybe less pain but it still looks good rather than no pain and doesn’t look good sort of thing”

Figure 2.4: General dimension of aesthetics relating to bra preferences and issues
(numbers in brackets are number of times this raw data theme was reported)

2.4.2.5 Fit

Fit was mentioned 56 times within the focus groups and interviews (Figure 2.5). Within the first higher order theme of bra fitting, the main raw data theme was ‘finding the correct bra fit is important’. The prospect of purchasing multiple bras of the same type when a good bra fit is obtained was discussed;
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“1: but that’s the point though isn’t it because once you find one it’s like great there’s actually one that fits
2: yeah I’ll go with that
1: and every colour and shade whatever in that one…because it works!”

Figure 2.5: General dimension of fit relating to bra preferences and issues (numbers in brackets are number of times this raw data theme was reported)

2.4.2.6 Purchasing Factors

Purchasing factors were mentioned 50 times with four higher order themes (Figure 2.6). Within the higher order theme of cost, most participants suggested that £25 was the highest price they would pay for one bra. One participant in particular spoke of her restriction to spend any more than £20 on a bra despite it being an ‘essential’ item of clothing:

“…I’ve often thought how I consider it to be a big, big deal to spend more than £20 on a bra whereas you wouldn’t think anything about spending more than that on other items of clothing…even though they are essentials and probably more important than what you are wearing on the outside…I seem to have a bit of a mental block about spending a lot of money on one”

The following brands were mentioned as places the participants shopped within the focus groups and interviews by the participants; Marks and Spencer’s, Debenhams, Panache, BHS, Tesco, New Look, Ann Summers, Primark, Freya, Triumph, Wonderbra, Bravissimo, John Lewis, La Senza, Asda, Next and Dorothy Perkins.
Bra preferences and concerns

Figure 2.6: General dimension of purchasing factors relating to bra preferences and issues (numbers in brackets are number of times this raw data theme was reported)

2.4.2.7 Fabric

The fabric of the bra was the least mentioned general dimension overall. There were four higher order themes within this dimension (Figure 2.7). The most common raw data theme within the higher-order theme of a dislike of bra stretch was that the bra fabric stretches and loses support. One participant said about her bras stretching:

“yeah like I’ve got two bras exactly the same size both used to fit, ones stretched slightly and you can put your hands in [hands fit inside the cups whilst wearing], I wear those at home when I’m not bothered about support…but yeah they stretch and can be uncomfortable…it’s because you haven’t got the support there”

Figure 2.7: General dimension of fabric relating to bra preferences and issues (numbers in brackets are number of times this raw data theme was reported)
2.4.2.8 Sports Bra Use

Additional to the bra preferences and concerns investigated, participants were also asked if they would wear a sports bra on a daily basis if it could help their breast pain. Results of frequency analysis found that only three (30%) participants said they would wear a sports bra on a daily basis. Five (50%) were unsure if they would wear a sports bra daily with some of these participants suggesting that it would depend on their outer clothing as to whether a sports bra would be appropriate. Two (20%) participants said they would not wear a sports bra every day.

2.4.3 Bra Fitting Services

There were four higher order themes (Figure 2.8) that emerged from the data under the general dimension of bra fitting services; sales assistants, inconsistent fittings, retailers and training. A total of 27 references to bra fitting services fell within the higher order themes. Under the higher order theme of sales assistants the raw data theme of ‘unhelpful bra fitters’ was the most reported. This covered pushy bra fitters and bra fitters who seemed to ‘not be bothered’ to help;

“the last time I had a bra fitting it was atrocious…she refused to believe me when I said I needed a 28 [UK under band size]…she was like “no you need a 30, you need a 30”… and you know the underwire is supposed to touch your breast bone…it was clear the bra wasn’t supporting me…do you know when you can tell someone just can’t be bothered?...I was just like I’ll figure it out myself…and got a perfect fit…I haven’t changed sizes since”

The second higher order theme related to inconsistent fittings, with the ‘bra fitter differences’ being most reported. These differences in fittings resulted in multiple bra sizes being assigned to one participant within a short time.

“...I’m not convinced in department stores that all of the women that do fittings are…really good at doing what they are doing, I mean different women giving me different sizes in a very short space of time…I’m not sure there is a lot of consistency with measuring either”
2.4.4 Perceived benefits of a bra prescription service

Participants were asked whether they perceived a benefit in a bra prescription service to help ease breast pain. This topic evoked a number of discussions detailed in Figure 2.9. There were five higher order themes established from the data; content, benefit, delivery of advice, format and regularity. A focus was placed on not only finding a good bra but also knowing what bra types to avoid;

“...if I had someone to say like this type of bra would help you or avoid that type of bra...just something to say this will make it [breast pain] easier, this will make it a bit better”

It was noted that participants reported wanting some breast health and breast pain advice alongside the advice on the types of bras to wear. There was only one participant that reported that she did not see a benefit to a bra prescription service.

Figure 2.8: Discussion points relating to bra fitting services (numbers in brackets are number of times this raw data theme was reported)
2.4.5 Activities that increased breast pain

Participants were asked to report the activities they felt caused their breast pain to increase. A total of 11 activities were mentioned by participants including activities of daily living and sporting activities; ‘running’ (n = 6), ‘general physical exercise’ (n = 5, activities not specified), ‘manual work using arms’ (n = 5, including housework and occupational activities), ‘walking down the stairs’ (n = 3), ‘jumping’ (n = 2), ‘lying down’ (n = 2), ‘walking’ (n = 1), ‘intimate activities’ (n = 1), ‘running for the bus’ (n = 1), ‘showering’ (n = 1) and ‘spinning classes’ (n = 1).

2.5 Discussion

The first aim of this study was to investigate the bra preferences and concerns experienced by women with larger breasts and breast pain. Frequency analysis showed comfort was the most reported general dimension for this cohort of women agreeing with the findings of previous research in older women (Risius et al., 2014). This indicates that comfort factor is important to women with larger breasts and breast pain. Comfort was expressed as both a preference and a concern, participants felt they needed the comfort, but were not always getting it from the bra. The level of comfort needed by participants varied as some preferred a looser bra or a bra with greater stretch to “give them room”, yet some participants still preferred lift and support which could conflict with comfort. Comfort was also related to different bra components, with under-wiring and straps being mentioned by participants as comfort problem areas of the bra. This emphasises the need to assess bra comfort across a number of a bra components (not just overall).
Support was the second most reported general dimension, this is different to previous research where support was reported third after aesthetics or fifth after the bra staying in place, fit and appearance under clothes (Risius, Thelwell, Wagstaff, & Scurr, 2012; Risius, et al., 2014), but is important as previous breast biomechanics research show an increase in breast support can reduce breast pain (Mason et al., 1999; Scurr et al., 2010). It is surprising that support did not rank higher than comfort due to the link with breast pain (as support increases, breast pain decreases), but perhaps the link is not well-known within the general public. Additionally, as these studies focus on movement-induced breast pain during exercise the findings may not be as applicable. The bra itself encapsulates or compresses the breast to limit the motion of the breast.

The participants in this study had large breasts (≥ D cup) (Turner & Dujon, 2005) and reported a lack of natural support was a problem. They also felt a bra was a necessity. The breast requires external support as the Cooper’s Ligaments and the skin provide limited support to the breasts (Page & Steele, 1999). The participants had an above average breast mass which increases the load on the internal supporting structures and consequently increases the need for external support in the form of a bra. Participants wanted compression, lift and bras to be designed with more support, including underwire and wider under bands. Research has identified that increasing support, compression and lift (elevation) does reduce movement-induced breast pain therefore support should be a key variable when prescribing bras to women with breast pain (Mason et al., 1999; McGhee & Steele, 2010a; Scurr et al., 2010). A supportive bra will ensure they do not experience excessive breast movement that causes movement-induced breast pain or exacerbates cyclical or non-cyclical breast pain.

The bra is a psychological symbol of self-image, sexuality and confidence as well as being a functional item of clothing that provides support to the breasts (Sukumar, 2007). Within the general dimension of aesthetics, some participants reported disliking the full cup shape, deemed essential and supportive to some, due to feeling old and unsexy. There has been no research published which identifies whether a particular everyday bra style is more supportive than another. It was interesting that one participant preferred to still experience some breast pain if she could wear a “nicer style” of bra instead of having no breast pain in a less attractive bra. This demonstrated a preference for aesthetically appealing bras and a concern for wearing less attractive bras despite the possible health benefits. This emphasises that the assignment of one bra to all women who suffer from breast pain in Wilson and Sellwood’s (1976) study may be inappropriate for a bra prescription and warrants further investigation into individually prescribed bras, incorporating wearer preferences in the bra choices. This also agrees with the suggestion presented in McGhee,
Steele, Zealey and Takacs’s (2013) study which proposed one bra style may not be adequately supportive for larger breasted individuals due to the large variation in breast volume and mass.

Participants within this study also mentioned how they wanted practical bras, basic colours, not too many bows and frills, and enough breast coverage. Yet despite this, participants still wanted the bra to provide them with a good shape and separation of the breasts. This indicated that although participants did not necessarily want aesthetically pleasing bras they still wanted their breasts to look good under clothing.

Tsaousi and Brewis (2013) investigated the perception of visible and hidden underwear which was an area brought up as concerns within a number of higher order themes within this study (appearance under clothes, dislike of bra transparency and bra appearance). Participants within the Tsaousi and Brewis (2013) study discussed how embarrassment can come from a bra being visible without intention and that the bra should be hidden. This agrees with findings from the focus group discussions within this thesis, as there was a preference not to wear see-through fabrics due to embarrassment if a shirt gaped. Also there was some discussion about purchasing bras that were plain and smooth to minimise any potential for bras to be seen under clothing.

The fit of clothing is a problem for many groups of women including the plus size market and the older generation (Otieno, Harrow, & Lea-Greenwood, 2005). Inconsistent sizing is a problem across clothing items and has been reported to affect the satisfaction of shoppers (Otieno et al., 2005). The bra market is just one of these areas that can cause problems. This was a concern discussed within the focus groups and interviews with many participants displaying dissatisfaction with the sizing and availability of larger bra sizes, as well as poor experiences with bra fittings services. The dissatisfaction of bra fit could demonstrate the problem with the traditional method of bra fitting, emphasised in previous research (White & Scurr, 2012), but remains the method used by many retailers. As this method of bra fitting was only designed to cater up to a D cup bra size (Greenbaum et al., 2003), the participants within the focus groups and interviews were >D cup and therefore more likely to experience problems. This advocates the use of the best fit method (White & Scurr, 2012) to improve the bra fitting experience for women with larger breasts. Participants brought up the idea of standardised training between stores and also encouraged retailers to provide knowledgeable and willing staff to help customers when buying bras. The health benefits of wearing a well-fitting bra have been widely promoted (McGhee & Steele, 2010b) and yet 70 to 100% of women (White & Scurr, 2012) still wear the incorrect size which may be due to some of the concerns reported by participants within this study.
Participants limited the amount they spent on bras, or used online marketplaces to buy more expensive bras for less. Price is an important factor when purchasing new clothes with a higher price often being perceived as a higher quality item (Dodds, Monroe, & Grewal, 1991). But despite this perception, one participant found it difficult to spend a lot of money on a bra even though she would spend a lot more on other items of clothing. This is important for developing the bra intervention within this thesis, as the bras selected must be a reasonable price to purchase outside of the study parameters.

The dislike of bra shopping was evident within the higher order theme of purchasing process and participants stated that it was time-consuming and often left until necessary. It is interesting to note that the women in the study were of larger cup sizes and therefore always deemed a plus-size in terms of bra sizing by many retailers. The poor shopping experience of these participants is reflected in a consumer study of which over half of size 16 and above consumers failed to answer a question regarding the enjoyment of shopping for clothes which may indicate similar dissatisfaction (Dodds et al., 1991). Some of the other higher order themes within other general dimensions (such as lack of available sizes and choice) may contribute to the dissatisfaction held by participants and improving these factors may have a positive effect on the bra shopping experience as a whole. Although these factors may not be able to be improved within scope of the bra intervention, providing the participants with a selection of bras to try and have assessed for appropriateness may go some way to address this dissatisfaction.

Only three participants said they would consider wearing a sports bra on a daily basis to ease their breast pain, therefore it may be more appropriate to design a bra intervention using everyday bras. This is despite the success of previous research (Hadi, 2000) for treating clinical breast pain with a sport bra, the research may not be relevant for all women. The type of sports bra assigned to women in this study is also unknown, encapsulation bras are good for support and often do not look like a traditional sports bra. The look of the traditional sports bra may have discouraged participants in this study from wanting to wear this type of bra on a daily basis.

The second aim of this study was to understand the perceived benefits of a bra prescription service for women with larger breasts and breast pain. All but one participant reported that they would find a bra prescription service useful. Participants suggested that this could take many forms including advice, help with finding a bra and could be both online (to make referring back to information easier) and face-to-face. It was interesting that participants not only wanted advice on appropriate bras, but also bras to avoid. Previous research used an educational booklet to provide breast health advice to adolescent girls (McGhee, Steele, &
Munro, 2010) and it was mentioned by one of the participants within this study that they found it difficult to provide their daughter with advice. Relating to the bra preferences and concerns raised by participants it was clear that bra purchasing is a difficult process partly due to the variability of bra sizing and manufacturing differences, educating women on these differences and the variability may reduce this concern. The overall aim of this thesis is to develop, pilot and evaluate a bra intervention for women with larger breasts who are experiencing breast pain. This type of bra intervention therefore, cannot be online. Educating women on bra styles, sizing and manufacturing differences is an additional intervention which could be applied at a later stage. It is well documented that bras can be effective at reducing breast pain, but there has been no RCT to confirm these findings. It is therefore important that one is conducted to provide the evidence-base for the current recommendations. The RCT however should only focus on the bra intervention itself as adding in an educational tool as well may confound the results. It is important that the outcome of the RCT can be attributed to a bra being prescribed rather than an educational tool. A separate RCT could investigate the effectiveness of educational tools alone or in conjunction with a bra prescription to assess whether combined, there is greater improvement in breast pain.

The final aim of this study was to investigate the daily activities that may cause an increase in breast pain for women with larger breasts and breast pain. The 10 activities mentioned incorporated a range of sporting and daily activities (spinning, running, jumping, and general physical exercise). It is well known within the literature that vigorous activities (sport and physical activities) such as running and jumping, cause an increase in breast pain and an increased level of breast support is needed (Bridgman et al., 2010; Mason et al., 1999; Scurr et al., 2010). The everyday bra does not provide adequate support to the breast to reduce breast pain sufficiently during these types of sport and physical activities (Mason et al., 1999; Scurr et al., 2010) and therefore are not recommended. The other activities mentioned by participants are activities of daily living e.g. showering and going up and down the stairs. Some of these activities cannot be resolved by a bra (e.g. showering, lying down) and others were only mentioned to be a concern for one participant (running for the bus, intimate activities, walking). The two remaining activities of daily living (walking up and down the stairs, and manual work) could be used to assess the effectiveness of everyday bras at reducing breast pain.

In conclusion, this chapter has established the bra preferences and concerns of women with larger breasts experiencing breast pain. The results of this study are specific to women with breast pain and represents the truth or reality of the participants who participated in the focus group and interviews. Comfort was the Key Performance Indicator (KPI) for this
Bra preferences and concerns

cohort. This was followed by support, which has been a KPI in previous research for reducing breast pain in exercising females (increases in support equated to decreases in breast pain). Establishing the KPI’s allows for a protocol to be developed to prescribe appropriate bras to women with larger breasts who are experiencing breast pain. The chapter met its second aim, as it established an interest in a bra prescription service and met the third aim by establishing the activities (walking, stair climbing, sweeping and reaching) that induced breast pain in this cohort.

Due to the wide variety of bras available on the market, the next steps for this programme of work are to use the results of this chapter to establish a selection of bras for use within the bra intervention. It is important that this is completed in a systematic manner as the bra market is vast and there are important factors to consider based on the results of this study/chapter such as cost, availability and styling factors. Once a systematic method has been developed it can be applied to the bra market to identify the bras which should be assessed within a bra intervention.
3 Chapter Three: Bra selection criteria to determine bras for the bra intervention study

3.1 Introduction

The previous chapter explored the bra preferences and concerns of women with larger breasts who experienced breast pain. This knowledge can be used to condense the extensive bra market for this cohort of women into a smaller and more manageable number of bras for inclusion in the bra intervention. This can be completed using the following systematic method for selecting the bras (Figure 3.1).

Establish cohort → Conduct focus groups and interviews with cohort → Establish key performance indicators, and assess whether higher order themes are objective or subjective → Determine criteria → Apply criteria

Figure 3.1: The process of determining a criterion for selecting bras for specific cohorts of women

3.2 Rationale

Consumer purchasing behaviour is the behaviour consumers use to purchase a product (Birtwistle & Tsim, 2005). For example, in mature women, style/garment cut, smartness and comfort were the top three influencing factors in purchasing formal and casual clothing (Birtwistle & Tsim, 2005). To establish important aspects of consumer purchasing behaviour, the method of using a criterion is widely used within clothing comparative research. This method can be used for choosing bras within the bra intervention.

A study conducted in 2002 saw consumers from the United States and Taiwan compared for clothing choices based on a set of 12 criteria using a survey based method (Hsu & Burns, 2002). This study aimed to understand the importance of factors, such as comfort and fit, on the purchasing process. Chen-Yu and Seock (2002) investigated the clothing store selection criteria used by adolescents and identified that cost was the most motivating factor.
for participants. They then developed a criterion for store selection based on previous research, obtaining results using a survey based method.

A focus group and interviews with larger breasted women who experienced breast pain (Chapter Two) identified that women wanted to have a choice of bras; however, research has identified that women need greater assistance in finding bras (Woollett et al., 2012). The previous chapter indicated that participants liked a variety of bras but felt there was a lack of choice. This suggests that a selection criterion that allows a range of bras to be assessed for suitability is needed to find a bra to relieve breast pain. Some bra preferences established (Chapter Two) were objective, and could be used to determine criteria to select a range of bras for use within breast pain intervention studies. Determining a suitable selection of bras can reduce; the time-consuming aspect of bra shopping, the potential for purchasing errors and help to find suitable bras without limiting choice. Despite the overall research philosophy of this thesis being a constructivist relativistic ontology, this chapter focuses less on the patients themselves, and more on an objective process, which follows a more positivist approach (Krauss, 2005).

3.2.1 Aims

1. To establish an objective criterion which could be used to determine a selection of bras which may be appropriate for women with larger breasts and breast pain based on the higher order themes from Chapter Two.

2. To apply this criterion to evaluate the current bra market to select bras for further assessment within subsequent chapters of this thesis.

3.3 Methods/Results

Higher order themes from Chapter Two were assessed for their appropriateness for use within a bra selection criterion (Table 3.1), the general dimensions have been ordered by the number of objective variables within the general dimension. Higher order themes were excluded (n = 24) if they could only be determined by individual preferences (e.g. comfort) as these would be assessed within the bra intervention itself with the selected bras. Additionally, higher order themes were excluded if they were objective measurements that could not be completed without being assessed within the laboratory (e.g. support and lift). To do this, it would involve purchasing all of the bras on the market, and assessing each of them, prior to selecting the bras for use within the bra intervention and therefore this is not practical. The subsequent list of criteria are then described in section 3.3.1.
Table 3.1: Appropriateness of higher order themes from Chapter Two in order of most to least appropriate for use within bra selection criteria for women with larger breasts and breast pain.

<table>
<thead>
<tr>
<th>General Dimensions</th>
<th>Higher-order themes from Chapter Two</th>
<th>Subjective (S) or Objective (O)?</th>
<th>Why/Why not?</th>
<th>Can be used in the criteria?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purchasing Factors</strong></td>
<td>Cost</td>
<td>O</td>
<td>Within the previous chapter most participants would not pay more than £25 for one bra, so cost will be limited to this.</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Brand Perception</td>
<td>O</td>
<td>This is individual specific but a list of potential brands/retailers were compiled from the focus groups/interviews</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Online or In-store Purchasing</td>
<td>O</td>
<td>Bra must be available in-store and within the Portsmouth Commercial Road shopping area</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Purchasing Process</td>
<td>O</td>
<td>Bras will be collated by researchers not participants</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Practicalities</strong></td>
<td>Appearance Under Clothing</td>
<td>S</td>
<td>This is individual specific</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Lack of Available Sizes</td>
<td>O</td>
<td>Bras will only be selected if they come in the full size range of 34 to 40, DD to G</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Lack of Choice</td>
<td>O</td>
<td>A selection of bras will be chosen which will provide participants with some choice</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Bra Longevity</td>
<td>O</td>
<td>The lifespan of a bra is dependent on the wash-wear cycle but the longevity of the bras availability in store can be assessed by purchasing bras which can be repeat purchases.</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Functional Requirements</td>
<td>O</td>
<td>Within Chapter One this related to the need to have a bra which was functional for the participants daily living and work; therefore this measurement is individual specific</td>
<td>No</td>
</tr>
<tr>
<td><strong>Fit</strong></td>
<td>Breast Size Differences</td>
<td>O</td>
<td>This is individual specific therefore cannot be catered for prior to fitting. This higher order theme included factors such as breast asymmetries and changes over the menstrual cycle</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Size Inconsistencies</td>
<td>O</td>
<td>A range of sizes will be available to participants allowing for inconsistencies for size to be assessed</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>General Fit</td>
<td>O</td>
<td>A range of sizes will be available to get the best fit for participants</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Feeling Secure</td>
<td>S</td>
<td>This is subjective feeling but can be minimised if a range of sizes is available to optimise bra fit</td>
<td>Yes</td>
</tr>
<tr>
<td>Support</td>
<td>Level</td>
<td>Description</td>
<td>Assessment</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>Reduction in Support when in</td>
<td>O</td>
<td>Participants will be provided with a bra to assess whether it helps to</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
<td>reduce their breast pain, not whether reducing support helps.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lift</td>
<td>O</td>
<td>This cannot be assessed pre-purchase</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Support in Sleep</td>
<td>S</td>
<td>Participants will be given an everyday bra to wear, sleep is not being</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>monitored</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Support</td>
<td>S</td>
<td>Supportive everyday bras will be chosen based on bra descriptors</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Design Requirements</td>
<td>O</td>
<td>As bras being assessed are already on the market the design of the bras</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>cannot be altered or requirements changed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression</td>
<td>S</td>
<td>This cannot be assessed pre-purchase</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Lack of Natural Support</td>
<td>S</td>
<td>Supportive everyday bras will be chosen</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

| Aesthetics                    |       |                                                                             |            |
| Shape of Breasts              | S     | This is individual specific                                                 | No         |
| Bra Appearance                | S     | This is individual specific                                                 | No         |
| Breast Coverage and Modesty   | S     | This is individual specific, but a range of bras will be chosen which may  | No         |
|                               |       | assist with this theme                                                       |            |
| How the Bra Makes you Feel    | S     | This is individual specific                                                 | No         |
| Style                         | O     | A selection of bras will be chosen and these may vary in style between     | Yes        |
|                               |       | manufacturers leading to a variety of choice for participants               |            |
| Comfort                       |       |                                                                             |            |
| Bra Component                 | S     | Bra comfort is subjective and individual specific                            | No         |
| Bra Tightness                 | S     | Bra comfort is subjective and individual specific                            | No         |
| Softer Fabrics                | S     | Bra comfort is subjective and individual specific                            | No         |
| General Comfort               | S     | Bra comfort is subjective and individual specific                            | No         |
| Fabric                        |       |                                                                             |            |
| Dislike of bra stretch        | S     | This may happen to bras over time, unable to assess the life span.          | No         |
| Fabric Firmness               | O     | This cannot be assessed pre-purchase                                        | No         |
| Dislike of Fabric Transparency| O     | This is a subjective opinion which should not be used to limit bra selection| No         |
| Breathability                 | S     | This cannot be assessed pre-purchase                                        | No         |
3.3.1 Consideration for Criteria

Using the results from Table 3.1 each higher order theme was explored further and is listed in order of appearance below.

3.3.1.1 Cost (higher order theme; cost)

Most participants within the focus groups and interview study (Chapter Two) stated they would normally pay around £20 for their bras (less if they were buying multiple bras in one shop) and their maximum spend would be £25. To ensure the majority of participants would be able to purchase the bras following the intervention study the maximum cost for the bras was set to £25. Some of the brands mentioned within the focus groups and interviews do not have any bras for less than £25 in their range, but participants had purchased some of these brands from online retailers offering discounts.

3.3.1.2 Retailers (higher order themes; brand perception)

Retailers that were mentioned negatively were removed from the selection process (see Table 3.3). A list of the retailers that bras were typically purchased from was compiled (from Chapter Two) and was the basis of the bra selection process (see section 3.3.2). Brands not mentioned within the focus groups and interviews were added if they met the other criteria in the succeeding sections and were available in some of the retailers mentioned (e.g. Playtex® is available in Debenhams®).

The previous chapter established that participants liked to see and feel the bras before purchasing. With this in mind the retailers that were based within local high streets or shopping areas were considered as a starting point for the bra selection. This was also to allow participants the ability to purchase additional bras. The local city centre shopping area in Portsmouth has a number of retailers that sell bras; Marks and Spencer®, Debenhams®, BHS®, Next®, Ann Summers®, New Look®, Tesco®, Primark® and H&M®. These stores are present (except Tesco – which is not necessarily present on the high street itself but is present within the towns) in all surrounding city centre shopping areas within a 20 mile radius of Portsmouth (Chichester, Winchester, Southampton, Fareham), suggesting that the local city centre shopping area is representative of the local area. This area was used to eliminate some brands and retailers that are less accessible to local women. For this to be applicable to other areas, the local retailers should be identified in the chosen area and they should be used to inform the search.

3.3.1.3 Purchasing (higher order themes; online or in-store purchasing and purchasing process)

Participants were asked where they purchased their bras and whether they typically shop online or in-store. Both types of shopping were mentioned by participants; however, not all
participants wanted to shop online. Some participants shopped online once they found a 
bra in-store that fitted and others shopped online due to the wider access to bras in their 
size. As participants liked the ability to try on, see and feel bras before purchase, it was 
determined that the bras must be available in the local city centre shopping area.

3.3.1.4 Size availability (higher order themes; lack of available sizes, 
general fit and feeling secure)

Bra cup sizes of a D and above are typically classed as ‘large’ in scientific studies (Brown, 
White, Brasher, & Scurr, 2014; Greenbaum et al., 2003; Lapid, De Groof, Corion, 
Smeulders, & Van Der Horst, 2013; McGhee et al., 2013; Scurr et al., 2010; Scurr, White, 
& Hedger, 2011). This study chose to include DD cup bras up to a G cup, as many lingerie 
ranges start and finish in these sizes (e.g. Marks and Spencer’s® larger cup size bra range 
is called “DD plus”). Additionally under band sizes 34 to 40 were chosen as these sizes 
were available across all brands. Therefore, a size range of 34 to 40 under band and DD to 
G cup size was selected.

3.3.1.5 Styling (higher order themes; lack of choice and style)

Although participants within the focus groups and interview study would like more colour 
choice and styles available to them, it was noted that participants chose practical bras and 
only occasionally were colourful bras purchased. It was decided that the bras selected 
should be available in at least one of these colours; black, white or nude, so they were 
practical for everyday use. The shape of the bras may vary between retailers, which would 
provide a range of styles for participants and would be beneficial as each participant may 
not suit the same style.

3.3.1.6 Long-term availability (higher order theme; bra longevity)

Size availability, lack of choice and poor bra size consistency were some of the main 
problems faced when purchasing a bra. Participants indicated that when they found a bra 
that was supportive, comfortable and ‘worked’ they were likely to purchase the same bra 
again. It was therefore important that the bras chosen were continual lines, meaning they 
were not seasonal trend bras, but bras which were available to purchase in the long term. 
This was assessed by asking sales assistants within stores for their long term (> 1 year) 
ranges and by also looking at the online reviews for the products which showed the length 
of time it had been available. Sales assistants were also approached to identify which bras 
they would recommend for support. Questions asked were; “What bras would you 
recommend from your range for support?”, “Are they part of your continual lines/ranges?” 
and “Will they continue to be available?”. It is however acknowledged that bras may 
inevitably be discontinued or updated.
3.3.1.7 Bra fitting services (higher order themes; size inconsistencies)
Bra fit is an important factor for health reasons as poorly fitting bras can initiate breast pain through bra discomfort (McGhee & Steele, 2010b), therefore it was decided that only retailers who offer a bra fitting service would be included. This will enable participants in the intervention study to receive bras that come from retailers that could provide further bra fitting advice in-store, although it is acknowledged that there may be issues surrounding bra fitting services (section 2.4.3).

3.3.1.8 Were the bras advertised for support? (higher order themes; general support, lack of natural support)
Higher levels of breast support help to reduce excessive breast movement and associated breast pain (Mason et al., 1999; Scurr et al., 2010). Alongside this, it is noted that support can be both a subjective and objective measurement and therefore the level of support provided by a bra cannot be determined by sight alone. Therefore, only everyday bras that were advertised specifically for support will be assessed in this study.

3.3.1.9 Next steps
Table 3.2 shows the final list of criteria to be used within the bra selection process.

Table 3.2: Final criteria for bra selection to be applied to the current bra market

<table>
<thead>
<tr>
<th>Higher Order Theme</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>Bras must be less than £25</td>
</tr>
<tr>
<td>Brands/Retailers</td>
<td>The brands or retailers to be investigated will be compiled from those mentioned within the focus groups and interviews chapter and those mentioned in a positive light will be included</td>
</tr>
<tr>
<td>Purchasing</td>
<td>Bras must be available on the Portsmouth high street and in-store</td>
</tr>
<tr>
<td>Size Availability</td>
<td>Bras must be available in the size range 34 to 40, DD to G</td>
</tr>
<tr>
<td>Styling</td>
<td>Bras must be available in one of the three basic colours (white, nude or black) but can have additional colours</td>
</tr>
<tr>
<td>Long-term availability</td>
<td>Bra must be continual lines which have been available for a period of time already</td>
</tr>
<tr>
<td>Bra Fitting Services</td>
<td>Stores must have a bra fitting service to provide further advice if necessary</td>
</tr>
<tr>
<td>Were the bras advertised for support?</td>
<td>Bra must be described as a support bra or recommended for support support?</td>
</tr>
</tbody>
</table>

3.3.2 Method of Selection
Figure 3.2 shows the process that occurred to determine the selection of bras for use in the bra intervention study using the established criteria. The order of the criteria was changed from the previous section (3.3.1) to one which improved the efficiency of the assessment of
the bra market. Brands/Retailers and whether brands were present on the Portsmouth high-street were assessed first and second as this would minimise unnecessary searching within inappropriate or non-accessible retailers. Once these were established the cost criteria removed any further inappropriate bras.

**Figure 3.2:** Process for selecting bras for women with breast pain and larger breasts

Brands were excluded when they failed to meet a stage of the selection process, bras from the retailers or brands that met all the criteria were then sourced (Table 3.3).
Table 3.3: Table of brands/retailers mentioned within the focus groups and whether they supply bras that meet the criteria

<table>
<thead>
<tr>
<th>Brand</th>
<th>STAGE 1</th>
<th>STAGE 2</th>
<th>STAGE 3</th>
<th>STAGE 4</th>
<th>STAGE 5</th>
<th>STAGE 6</th>
<th>STAGE 7</th>
<th>STAGE 8</th>
<th>OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative brand perception?</td>
<td>Available on the high street?</td>
<td>Bra available for less than £26?</td>
<td>Available in full size range?</td>
<td>Bra Fitting Service Available?</td>
<td>Advertised for support?</td>
<td>Has bras that are available long term?</td>
<td>Basic Colours? (Black, White or Nude)</td>
<td>Included in next stage of search?</td>
</tr>
<tr>
<td>M&amp;S®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Debenhams®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>BHS®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Tesco®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>New Look® - Kelly Brook</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Ann Summers (Knickerbox)®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Primark®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Panache®</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Freya®</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Triumph®</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Wonderbra®</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Bravissimo®</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>John Lewis®</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>La Senza®</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Asda® - Katie price range</td>
<td>No</td>
<td>Discontinued Line</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Next®</td>
<td>Yes</td>
<td>Excluded due to negative brand perception within the focus groups and interviews</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Dorothy Perkins®</td>
<td>Yes</td>
<td>Excluded due to negative brand perception within the focus groups and interviews</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
The final retailers chosen were Marks and Spencer®, Debenhams® and BHS®. These retailers provided support bras that fitted all the criteria determined. Debenhams® is a department store containing a wide range of brands. A search for bras within Debenhams® included all their available ranges and resulted in bras selected from the Playtex® brand as well as their own Gorgeous by Debenhams® range. Marks and Spencer® and BHS® do not have any external brands within their store so the bras within their store are their ranges only.

Within Marks and Spencer® and Gorgeous by Debenhams® ranges there were multiple bras that met all of the criteria. Once bras were identified they were assessed for cost and the bra size range to ensure they conformed to the other criteria. Support level was also assessed using the online and in-store bra descriptions. The sales assistants within the stores recommended the Floral Lace bra and the Total Support non-wired bra within Marks and Spencer's® and the Comfort T-shirt bra and Embroidered Mesh bra within the Gorgeous by Debenhams® range. Within the BHS® and Playtex® ranges only one bra for each brand met all criteria and thus these bras were selected. A total of six bras met the criteria in sections 3.3.1 and 3.3.2. These bras were from Marks and Spencer® (n = 2), Gorgeous by Debenhams® (n = 2), Playtex® (available in Debenhams®) (n = 1) and BHS® (n = 1) (Table 3.4). The bras vary in shape and styling with full cup and balcony bras, both padded and non-padded, and wired and non-wired bras.
Table 3.4: Bras from each of the brands that met all criteria for use within a bra prescription. Bra descriptions and pictures given to show the range of styles obtained.

<table>
<thead>
<tr>
<th>Front</th>
<th>Back</th>
<th>Name</th>
<th>Brand</th>
<th>Cost</th>
<th>Shape</th>
<th>Underwired?</th>
<th>Moulded?</th>
<th>Fabric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bra 1</td>
<td></td>
<td>'Cross your Heart' Bra</td>
<td>Playtex</td>
<td>£24.00</td>
<td>Full Cup</td>
<td>No</td>
<td>No</td>
<td>79% Polyamide, 10% Cotton, 11% Elastane</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Embroidered Mesh Bra</td>
<td>Gorgeous by Debenhams</td>
<td>£24.50</td>
<td>Full Cup</td>
<td>Yes</td>
<td>No</td>
<td>48% Polyamide, 46% Polyester, 6% Elastane</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comfort T-Shirt Bra</td>
<td>Gorgeous by Debenhams</td>
<td>£19.50</td>
<td>Balcony</td>
<td>Yes</td>
<td>Yes</td>
<td>59% Polyamide, 29% Polyester, 12% Elastane</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Voluptuous Cotton Mix Smooth Moulded Bra</td>
<td>BHS</td>
<td>£14.00</td>
<td>Full Cup</td>
<td>Yes</td>
<td>No</td>
<td>42% Nylon, 31% Polyester, 14% Elastane, 13% Cotton</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DD+ Floral Lace</td>
<td>Marks and Spencer</td>
<td>£16.00</td>
<td>Full Cup</td>
<td>Yes</td>
<td>No</td>
<td>87% Polyamide, 13% Elastane</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total Support</td>
<td>Marks and Spencer</td>
<td>£18.00</td>
<td>Full Cup</td>
<td>No</td>
<td>No</td>
<td>48% Cotton, 37% Polyester, 12% Elastane, 3% Viscose</td>
</tr>
</tbody>
</table>
3.4 Summary

Applying the criteria developed within this chapter, resulted in six everyday bras that met criteria for further use in the bra intervention. The bras met the criteria for; brand, cost, size availability, bra fitting services, being advertised for support, bra longevity and colour.

The three retailers which met the criteria were Marks and Spencer's®, BHS® and Debenhams® (Gorgeous by Debenhams® and Playtex® ranges). The cost of the bras that met the criteria were between £16.00 and £24.50, a large proportion of the brands mentioned within the focus groups and interviews had bras excluded due to the cost (>£25). The selected bras were all available in the full size range (34 to 40, DD to G). A number of bra ranges were excluded due to the lack of either the 34 or 40 under band sizes or because ranges stopped before a G cup.

Despite all bras being classed as ‘support’ bras, there was an assortment of styles (Table 3.4) providing an element of personal choice, which was preferred when choosing bras. For example, a selection of bras with both wiring and non-wiring is useful as it provides more options for the participants within the bra intervention. The shape of the bras varied, with balcony and full cup bra shapes. The fabrics within the six everyday bras have less than 20% elastane. Elastane are the stretch fibres of the bra and they make the fabric more comfortable to wear (Senthilkumar, Anbumani, & Hayavadana, 2011).

In conclusion, this chapter has established a criterion to select bras using data from the focus groups and interviews study (Chapter Two). This method is novel and has allowed for the selection of six everyday bras for women with larger breasts who are experiencing breast pain, meeting aim two. This has enabled the reduction of a large, confusing market place to be narrowed down to a smaller selection of bras.

The next stage of this thesis will continue the development phase of the MRC guidelines by establishing the method of prescribing bras. The next chapter will review existing of methods of assessing the bra KPI’s established in Chapter Two to determine their suitability for use within a bra prescription session for women with larger breasts who experience breast pain.
Chapter Four: Methods to assess the appropriateness of everyday bras for use within the bra prescription session

4.1 Methods to measure the Key Performance Indicators

Within the focus groups and interviews (Chapter Two) seven KPI’s were established; comfort, support, practicalities, aesthetics, fit, purchasing factors and fabric. These KPI’s were examined and purchasing factors, practicalities and fabric were used in the selection of the bras (Chapter Three). The remaining four KPI’s are individual specific; comfort, support, aesthetics and fit, and therefore will be used to assess the appropriateness of the bras for each patients within a bra prescription session. This session will ensure each bra is assessed objectively and subjectively on each participant, with a view to prescribing the most appropriate bra.

4.1.1 Comfort Methods

Research has determined that within the bra design process, comfort is one of the key requirements of the bra (Hardaker & Fozzard, 1997). Typically, wearer trials are completed to assess whether a bra is comfortable. Comfort is a perceptual measure and relates to the fit and shaping of a garment, as well as the figure of the wearer (De Klerk & Tselepis, 2007). De Klerk and Tselepis (2007) noted that some garments may be suitable for some figures or body shapes but not for other body shapes. This is related to bra comfort as the breasts are not a rigid structure. Breasts can be different shapes and can be positioned differently on the chest wall (Chan, Yu, & Newton, 2001). This makes designing a bra to suit all females difficult. Therefore, the comfort of garments should be based on individual perception of comfort.

There are a number of models for clothing comfort. One model, featured in a review by Kamalha, Zeng, Mwasiagi and Kyatuheire (2013), although developed in the 1970's by Pontrelli (1977, based on the model by Fourt and Hollies, 1970 cited by Kamalha et al., 2013), provides a good overview of what contributes to comfort perception. Physical factors (such as environment, physical activity level and clothing and characteristics) and psycho-physiological factors (such as a person’s state of being, purpose/end use of clothing, fashion/design/style and garment tactile aesthetics and fit) contribute to what Pontrelli called; stored person modifiers. These modifiers can then be assessed by the wearer to allow them to come to a conclusion about their comfort perception. This indicates that in subjective measures of comfort, wearers are likely to have filtered through a number of factors prior to giving their overall rating of comfort. It is therefore important that participants are given enough time to process their thoughts about bra comfort.
The subjective comfort of clothing and footwear is often measured using various types of rating scales (Cardello, Winterhalter, & Schutz, 2003; Lawson & Lorentzen, 1990; Miller, Nigg, Liu, Stefanyshyn, & Nurse, 2000; Mün德mann, Stefanyshyn, & Nigg, 2001). Previous studies investigating clothing comfort have used a combination of descriptors and graphic rating scales to determine the comfort of clothing (e.g. scratchiness, smoothness etc.). However, there is opportunity to improve upon this measurement for comfort. When comparing rating scales, the Visual Analogue Scale (VAS) is often thought to be the most sensitive self-reporting measure and is often used in pain research (Breivik et al., 2008; Huskisson, 1974). These scales allow the user to mark a point on the line where they rate their level of pain between two extremes (Mattacola & Perrin, 1997). The VAS has been used extensively to measure breast pain, both in clinical and non-clinical research (Ader & Shriner, 1997; Colak, Ipek, Kanik, Ogetman, & Aydin, 2003; Gopinath et al., 2005; McGhee et al., 2010; McGhee, Steele, & Power, 2007; McGhee et al., 2013; Wood, Cameron, & Fitzgerald, 2008), and this demonstrates that despite the scale being reported as difficult for new users, its routine use suggests that with instruction, respondents can use the scale effectively.

Visual analogue scales have been reported as reliable (Downie et al., 1978), have been validated in a variety of research, and the scale has been adapted to fit the cohort of participants in different studies, e.g. coloured scales (Bromley, Emerson, & Caine, 1998), curved line scales (McDowell, 2006) and vertical versus horizontal scales (Downie et al., 1978; Ogon, Krismer, Söllner, Kantner-Rumplmair, & Lampe, 1996). In general, the VAS is used horizontally (as a 10 cm line) as vertically the perception of the scale can be distorted resulting in errors (Dixon & Bird, 1981). McCormack, Horne and Sheather (1988) reported that the lack of discrete numbering in the VAS was less likely to cause the clustering of scores around a particular number making the data collected from this type of scale less biased than numeric or graphic rating scales.

Mün德mann et al. (2001) assessed the comfort of shoe inserts based on multiple VAS. Bra comfort could also be assessed across a number of typical bra components, rather than by one VAS measuring overall comfort. The bra is a complex garment comprising of more than 20 bra components (Chan et al., 2001). Many of these components can affect the levels of comfort as they alter the fit of the bra and may be inappropriate for certain breast shapes. From the list of 20 components in the paper by Chan et al. (2001) eight components (Figure 4.1) have been considered important to measure the comfort of everyday bras; under band, underwire (or front portion of the under band if the bra was non wired), side of bra, centre-piece, fabric, cups, hook and eye and straps. Each of these components could cause friction on the skin and could alter the comfort of the bra.
A pilot study (Appendix C) was conducted to assess the reliability of VAS for bra comfort. The aim was to assess the reliability of a VAS for breast pain and bra comfort using the t-test, ICC and Bland-Altman 95% limits of agreement. Results showed the VAS was reliable for measuring bra comfort across the eight bra components. The VAS was, therefore deemed appropriate to assess bra comfort.

To appreciate the level of comfort the bra provides, the bra should be worn during activity before the measurement is taken. Previous research has assessed comfort following a period of activity (Bowles & Steele, 2013; Lawson & Lorentzen, 1990; Mümdermann et al., 2001).

### 4.1.2 Methods to assess support

Within previous breast biomechanics literature breast support has been assessed objectively to measure a reduction in: breast range of motion (ROM), velocity and acceleration. These reductions have been positively related to a reduction in breast pain (Mason et al., 1999; Scurr et al., 2010).

An objective assessment of breast support needs a “baseline” measurement to assess maximum breast movement, and then consequently this baseline measurement is used to show the effectiveness of different bras. Typically breast biomechanics studies utilising a healthy and fit population use a bare breasted (no support/bra) condition to act as the ‘maximum breast movement’ baseline measurement during specific exercises (Bridgman et al., 2010; Mason et al., 1999; Milligan, Mills, & Scurr, 2014; Milligan, Scurr, Mills, & Wood, 2001).
Development of the bra prescription session

2011; Mills, Loveridge, Milligan, Risius, & Scurr, 2014b; Risius, Milligan, et al., 2014; Scurr et al., 2009). Range of motion, velocity and acceleration reduction is typically presented as a percentage reduction compared to the baseline measurement. This is a consideration for the next stage of the study, as the patient’s that will be included will have breast pain and will be of a larger bra size than typically used within the breast biomechanics literature. In this thesis baseline breast movement will be calculated from the patient’s own everyday bra and not a bare-breasted condition. This will also provide evidence about how the prescribed bra is more appropriate than the bra patients had been wearing. It is acknowledged that the level of support being provided by each patient’s own everyday bra will vary, but, this was not deemed to be an issue as the prescription is a within-participant design. This means that participants will be prescribed a bra based on the improvement it can make to that individual. It is possible that the participants own bra may appear more supportive than the bras which have been selected in Chapter Three. This could occur if a participants own bra is poorly fitting, and consequently the breast tissue is compressed against the body, providing the illusion of support. Additionally, as the bra prescription will be made across the four KPI’s, a bra may score highly for the other three KPI’s but lower for support, but still get prescribed.

Similar to bra comfort, support could also be assessed subjectively using rating scales, allowing participants to provide their opinions on the bras. For most women, they would assess the level of support provided by their bras independently, either when trying the bra on within a shop or at home. This indicates that a subjective assessment is also appropriate alongside an objective assessment.

4.1.2.1 Activities

The activities identified within Chapter Two were brisk walking, going up and down the stairs and manual work/housework. The focus of the bra prescription session is the performance of the bra and so the order of the bras will be randomised but the activities will remain in the same order.

4.1.2.1.1 Brisk Walking

Previous research (Murtagh, Boreham, & Murphy, 2002) reported a brisk walking pace (males and females) of approximately 6.4 km\(^{-1}\) (1.79 ± 0.19 m s\(^{-1}\)) on a treadmill with an observed walking speed of approximately 5.6 km\(^{-1}\) (1.57 ± 0.18 m s\(^{-1}\)). Previous breast biomechanics research using female participants has used a brisk walking pace of 6 km\(^{-1}\) (Risius, 2012). As the participants in this programme of work will also be females aged 18 years and over, as were the participants in Risius (2012), a maximum brisk walking speed will be 6 km\(^{-1}\). The pace of brisk walking will be self-selected and participants keep this
speed the same across all bra trials. Participants will be allowed some familiarisation time to select the speed they wish to walk at.

### 4.1.2.1.2 Stair Climbing/Descending

Previous research on older participants with hip implants has had participants climb stairs up to six times (Bergmann et al., 2001). The data collected in this study will analyse the ascent and descent individually, participants will therefore be requested to complete the stair climb and descend three times (providing three ascents and three descents). The average home has a staircase with 13 steps, three ascents up the stairs used within this study will ensure the participants climb almost a full staircase (12 steps ascending and 12 descending) without completing more stairs than a normal staircase (Figure 4.2).

**Figure 4.2: Stairs used in bra prescription session**

Within the study by Bergmann et al. (2001) participants were verbally advised on their speed and it was not controlled, however, there is opportunity in this study to control speed/pace using a metronome. As per the walking trial participants will be instructed to self-select a stepping speed, at a brisk pace and the metronome (SQ50V, Seiko; Japan) will maintain consistency between trials.

### 4.1.2.1.3 Manual Work/Housework

Two manual work/housework activities were determined as they have been used to represent daily activities in previous breast health research (Risius, 2013); sweeping and reaching. Other activities were considered, however, they either; included the same activities (stair climbing/sweeping/reaching), were variations of these activities (putting shopping away in cupboards/walking in a crowded place) or the activities were functional in nature (getting in and out of bed/showering) and thus some activities would not necessarily be completed in a bra (Pincus, Swearingen, & Wolfe, 1999; Powell & Myers, 1995). The sweeping/reaching activities were determined to have the greatest arm ROM compared to the other activities. Therefore, there may be some movement of the bra straps which could affect bra comfort.
4.1.2.2 Position

Previous research has identified that compression and elevation during exercise can reduce movement-induced breast pain (McGhee & Steele, 2010a), indicating that breast position may be an influencing factor in reducing breast pain. Currently there is no literature to suggest whether breast position improves cyclical, non-cyclical or extramammary breast pain. Aspects of breast position were discussed within the focus group and interviews (Chapter Two) for example compression, and the context it was reported contradicted the previous research, as women felt that compression increased breast pain. As there may be a link between breast position and breast pain, it should be monitored but not contribute to the bra prescription.

4.1.2.3 Marker placement

To measure bra support objectively, participants will have their breast ROM, velocity and acceleration measured using optoelectronic cameras (Oqus 300, Qualisys, Sweden). Participants will have markers placed on their upper body and feet for the markers to be tracked in three-dimensional (3D) space at 250 Hz. The most recent marker placement for measuring breast biomechanics was developed by Mills, Loveridge, Milligan, and Scurr, (2016). This marker placement has improved upon the earlier marker placements (Scurr et al., 2009; Scurr, White, & Hedger, 2011) and is the ISBS recommended placement for torso markers (Mills et al., 2016). The marker set (Figure 4.3) is more stable than the earlier marker set (Scurr, White, & Hedger, 2011) which used the rib markers and sternal notch to create a torso segment due to movement of the soft tissue. Additionally Mills et al. (2016) reports that due to the additional markers between the suprasternal notch (STN) and Xyphoid Process (XP) markers and between the C7 and T8 markers, at least three markers will always be seen by the optoelectronic cameras as they will not all be obscured by bras. A final benefit of the new marker set, is that due to the positioning of the torso markers, the superiorinferior axis that is generated at the origin point is at an almost vertical positioning, compared to a backwards tilt seen in the earlier marker set (Mills et al., 2016). This means the data collected in the superiorinferior direction for breast ROM will be more representative than data collected previously as the backwards tilt significantly altered the magnitude of the breast ROM in the superiorinferior direction (Mills et al., 2016).
Additionally, one marker will be placed on the bra in-line with each nipple which will be used to represent the breast itself, and consequently this marker will be used to assess breast movement relative to the torso segment (which is made up of the other six markers). Chen, Wang and Jiang's (2012) study found the largest breast motion was at the nipple, but it was not significantly different to three other markers placed on the breast. They concluded that the nipple was a good representation of breast motion and consequently validated the use of this method (Chen et al., 2012). Along with the markers on the torso and breasts, one marker will be placed on the left and right lateral aspect of the heel. This will allow gait to be tracked during walking (Zeni, Richards, & Higginson, 2008) (see section 4.1.2.5 for the identification of gait cycles).

One consideration for the marker placement is the positioning of the XP and T8 markers, these typically sit where the bra centre piece (XP) and under band clasp (T8) are. Where possible the markers will not be moved and will remain on the skin. Should markers fall off they will be replaced and the location of the markers found again. If the landmark is completely obscured by the bra, it will be placed on top of the bra in line with the landmark as per the nipple markers.

4.1.2.4 Procedural considerations

A pilot of the bra prescription session was completed with the activities listed in section 4.1.2.1. The lab was set up (Figure 4.4) to ensure the treadmill and steps were in the field of view of the eight optoelectronic cameras (Oqus 300, Qualisys, Sweden) needed to capture the field of view. Cameras were placed on a ceiling rig to ensure they were not moved during the trials and so that the field of view was consistent. To minimise disruption in the laboratory and to ensure smooth transition between activities, a space was provided next to the steps for the sweeping and reaching activities. This allowed for the treadmill and
steps to remain in place. The area was calibrated using a 300 mm calibration wand and L frame (Qualisys, Sweden) to ensure the residual was less than 1mm.

![Laboratory set up](image)

**Figure 4.4:** Laboratory set up. C = camera

An additional practical consideration was the length of time or number of times an activity is completed in each bra. Previously, studies have assessed breast biomechanics over five gait cycles (Scurr et al., 2009) and this will be replicated in this thesis. Participants will be asked to walk for two minutes, with the last 30 seconds of walking recorded. For the steps, data were collected on the ascent and descent separately (see section 4.1.2.5 for further detail on gait cycle identification for stair climbing and descending). This means that one complete ascend and descend will equate to two trials.

Participants have been previously asked to sweep a 1 m² area of floor to maintain consistency between trials (Risius, 2012). This method will also be used within the bra prescription session. Within Risius's (2012) doctoral thesis participants were asked to sweep for one minute. The one minute duration was piloted, however, it was deemed too lengthy for assessing comfort (as it was being considered in combination with the other activities) and thus was reduced to 30 seconds.

The reaching activity was also adapted as participants were asked to reach from their sides unilaterally to a point marked on the wall (Risius, 2012). Within Chapter Two, manual work was described as putting away the shopping or lifting heavier items, which would most likely be completed bilaterally. Therefore, for the bra prescription session, participants will be asked to reach into the air bilaterally, three times, starting from the floor (in a squatting position) and then both standing and reaching at the same time. This is to replicate a movement closer to daily activities, for example, putting away shopping. To maintain
consistency between trials, participants will be asked to reach as high as possible each time, and touch the floor when squatting down.

4.1.2.5 Data analysis considerations

Following the bra prescription session markers will be identified in Qualisys Track Manager Software (QTM, Qualisys, Sweden) and all data will be exported as a C3D file. The C3D files will then be used within Visual 3D (V3D) software for analysis (C-motion, Version 5, USA). Within V3D, the static file is linked to each of the dynamic trials. Pipelines are then created in the software to calculate breast kinematic data (range of motion, velocity and acceleration) in three dimensions (X, Y and Z).

4.1.2.5.1 Model development

Participants will initially be asked to stand in the anatomical reference position in the field of view of the optoelectronic cameras (Oqus 300, Qualisys, Sweden) for a two second static capture to be taken. Visual 3D requires both static and motion files (from the walking and stair activities) to be inputted into the workspace and attributed to each other. An initial model was created within V3D for this thesis. This identified the origin point for which the markers will be referenced to. This origin point was on the STN marker. To create this model, two virtual landmarks were created in V3D, these were projected anteriorly to the C7 and T8 markers. The model was then created using these landmarks and the original C7 and T8 markers. The additional thorax markers (33%STN, 50%C7, STN, XP) were used as tracking markers to add stability to the model. Creating these landmarks allows the axis to sit directly in line with the STN marker (Figure 4.5).

![Figure 4.5: Original model developed for assessing breast motion within this thesis. Grey markers = projected markers. Black markers = torso markers. White markers = Nipple and rib markers.](image-url)
This model however, was not considered appropriate for assessing breast motion within this thesis. Despite the origin being directly on top of the STN marker, the local co-ordinate system axes were tilted backwards meaning that the torso superioinferior axis is not in a true superioinferior position. This means the magnitude of the superioinferior ROM appears to be smaller than it actually is as some of the movement is absorbed by the tilt of the body. The anatomy of the participant will also affect the measurement, as the participant’s torso structure may cause a larger or smaller tilt.

The model was therefore revised to follow the recommendations within Mills, Loveridge, Milligan and Scurr (2016). The chosen model for this thesis put the origin point at the mid-point between the C7 and STN points (Mills et al., 2016). This updated model uses the STN and C7 markers alongside the XP and T8 markers. The revised model improves the tilt of the axis so that the superioinferior axis (blue) of the local co-ordinate system is tilted forward and is as close as possible to a true superioinferior position (Figure 4.6). This will increase the consistency across participants. The model will then be applied to allow for a pipeline to be run and data to be analysed.

**Figure 4.6:** Original and revised models piloted for this thesis. The revised model is the model chosen to be used within the bra prescription sessions. Grey markers = projected markers. Black markers = torso markers. White markers = Nipple and rib markers.

### 4.1.2.5.2 Identification of gait cycles

There is literature that reports the identification of gait cycles for walking using the point where the foot velocity moves from a positive to negative value in the anteroposterior axis (Zeni et al., 2008). Zeni et al. (2008, p. 711) reported this method was a “simple and effective velocity-based algorithm to determine gait events on a treadmill”. This method has been
widely used in breast biomechanics studies (Milligan et al., 2014; Mills, Risius, & Scurr, 2014; Risius, Milligan, et al., 2014; Scurr et al., 2010; White, Mills, Ball, & Scurr, 2015) and will be used within this thesis. Within-participant variance in breast displacement was assessed within Scurr et al. (2009) using typical error of measurement and the coefficient of variance analysis. Scurr et al. (2009) found that within-participant variance in breast displacement over five gait cycles was low (0.9%CV SD=0.6%CV), indicating the suitability of using five gait cycles to show representative breast movement.

Identifying gait cycles is more complex for stair climbing and descending. Three methods of collecting breast biomechanics data during stair climbing were considered; identifying an event on every step (floor to step 1, step 1 to step 2 etc.), identifying an event every two steps (each gait cycle in effect e.g. right foot to right foot) or to assess the ascent as a whole and the descent as a whole (Figure 4.7). Previous research used instances of foot contact during stair climbing to assess hip contact forces and gait patterns in older people with hip implants (Bergmann et al., 2001).

![Figure 4.7: The methods considered for the placement of event markers during the step activity. The y axis represents the position of the STN marker in the superioinferior direction from the origin point of the global co-ordinate system. Each line on the figure represents an event marker placed in the data.](image)

It was decided through piloting that to replicate a gait cycle as closely as possible a virtual event marker would be placed on the data within V3D when the participant was stood on the floor just prior to movement of the STN marker and when they stepped onto the third step. The event markers were then placed at the start of the ascent, as the sternal notch starts to move vertically upwards (the dominant foot would be off the floor and moving towards the first step), the second event marker would be placed on the third step (the
dominant foot will be on the third step and the non-dominant foot will be moving towards the top step) (Figure 4.7). The vertical motion of the STN marker was used to identify the steps as this marker displayed a consistent pattern during the pilot testing. The lateral aspect of the heel marker was not chosen for the step activity as the lead foot would differ between participants. This would then be repeated as the participant descended the steps. Event marker placements were then automated using the height of the steps (~20 cm). The sternal notch marker at the start of the ascent will need to be adjusted within the data to accommodate for participants differing heights, each event marker would then be placed on the second step (when a 40cm increase in sternal notch vertical position occurred). This is to ensure the event markers are in the same place for each participant.

4.1.2.5.3 Dominant versus non-dominant breast

An additional consideration was whether breast ROM, velocity and acceleration would be calculated from data from one breast, or an average of both breasts. Previous breast biomechanics research has suggested collecting data from both breasts, determining whether there is a dominant and non-dominant breast and then making a decision to take data from one or both breasts (Mills et al. 2014).

It was important to note that breast pain can occur unilaterally or bilaterally, and until participants were recruited the researcher would not know the laterality of their breast pain. There was therefore, an option to assess the breast/s that they were experiencing breast pain. To do this, the data on each breast would have to be analysed individually to identify a dominant breast using one pipeline. If a dominant breast is identified, another pipeline would be needed to analyse the dominant breast data. If no dominant breast was identified, a third pipeline would be needed to analyse the data across both breasts. These three pipelines would be needed for the walking activity and another three for the stair activity. For the stair activity this presents an additional delay as each event marker has to be manually identified. All of the other measurements being taken in this session (comfort, subjective support, aesthetics and fit) being assessed bilaterally, previous research has identified no significant different in breast range of motion between the left and right breasts (Chen et al., 2012; McGhee et al., 2007; Scurr, White, & Hedger, 2011). It was therefore decided that it would be most appropriate to assess an average of both breasts for objective support and provide an average ROM, velocity and acceleration.

4.1.2.5.4 Filtering

Previous breast biomechanics studies, which assessed the level of support provided by bras, have typically used low pass Butterworth filters on kinematic data ranging from 6 Hz to 13 Hz depending on the type of activity being completed (Haake et al., 2012; McGhee &
Steele, 2010a; A. Milligan, Mills, & Scurr, 2014a; Mills, Lomax, Ayres, & Scurr, 2014; Mills, Loveridge, et al., 2014b; Mills, Loveridge, Milligan, Risius, & Scurr, 2014a; Mills et al., 2016; Mills, Risius, et al., 2014; Risius, Milligan, et al., 2014; Scurr, White, & Hedger, 2011; Scurr et al., 2010; Scurr, White, Milligan, Risius, & Hedger, 2011). Giakas and Baltzopoulos (1997) assessed different types of filtering and suggested that the Butterworth filter is good for assessing displacement and velocity data; however, a General Cross Validation (GCV) quintic spline filter is more appropriate for displacement and acceleration data.

Butterworth filters have a cut-off frequency to remove noise (Winter, 1990). There may be a need to compromise on cut-off frequency when choosing a Butterworth filtering technique (Winter, 1990). There is a potential loss or distortion of data should the cut-off frequency be set too high, conversely, setting the cut-off frequency too low may lead to noise being incorporated into the data (Challis, 2008; Winter, 1990). A spline filter, essentially works as a line of best fit, which attempts to fit a curve to the data points (Winter, 1990). A spline filter uses inflection points in the data to fit the spline, taking into account smaller sections of the data rather than the entire signal (Winter, 1990).

This thesis is incorporating walking, but also a stepping activity. A filtering investigation was conducted during a pilot test using a participant of a 34 under band and a DD breast cup size. Visually, little difference in breast ROM, velocity, and acceleration was observed between the Butterworth (6 Hz) and GCV quintic spline filtering techniques during the walking and stair activities. However, upon inspection of the data, the GCV quintic spline filter resulted in lower average breast ROM, velocity and acceleration values across five gait cycles (walking), three ascends and descends right foot to right foot (stepping activity) and averaging across both breasts. A recent breast biomechanics study quantifying gravity-induced skin strain used a GCV quintic spline filtering technique to analyse the 3D marker co-ordinate data (Sanchez, Mills, Haake, Norris, & Scurr, 2017). As the GCV quintic spline resulted in lower values across ROM, velocity and acceleration it was decided that this filtering technique would be used in this thesis as it is likely to incorporate less noise than the Butterworth filter.

**4.1.2.5.5 Outputting objective support**

Objective bra support data (ROM, velocity and acceleration) will be calculated as a percentage reduction compared to the same data in the patients everyday bra. This will give a percentage value for each of the testing bras and will demonstrate how each of the testing bras are performing relating to ROM, velocity and acceleration reduction compared to the participants own bra. A greater percentage value for each of these variables, indicates increased support from the bras.
4.1.2.6 Methods for assessing subjective support

Participant’s perception of how supportive each bra is will be assessed at the start (using a VAS) of the bra prescription session once an appropriate bra fit is found. This is to replicate the subjective assessment of breast support that women would typically undertake when trying on bras in a shop.

4.1.3 Aesthetics

Aesthetics are an important consideration for women when purchasing bras. There may be practical or health related reasons why a bra is worn (Hume & Mills, 2013; McGhee & Steele, 2010b), or the reasons may link to aesthetics such as; enhancing appearance, increasing self-esteem, visual/sexual appeal or fashion (Hume & Mills, 2013; Tsaousi & Brewis, 2013). With this in mind, it is important that during the development of a method for prescribing bras for women with larger breasts who are experiencing breast pain, that aesthetics are considered. For any type of clothing, aesthetics are a subjective measure. Aesthetics will not reduce breast pain, but aesthetics may influence the adherence to the treatment. Adherence to a protocol or treatment in randomised controlled trials is important to assess effectiveness, whether this is a drug treatment or other form of treatment (in this case a bra) (Vermeire & Hearnshaw, 2001). Chapter two highlighted the importance of aesthetics and reported that some participants may willingly continue to experience breast pain to “look good”, so considering aesthetics, may allow the participants some control over the bras they are assigned and thereby reduce the number of drop outs or poor treatment adherence.

Previous research has used rating scales to identify opinions on clothing. Otieno et al. (2005) used Likert Scales when asking participants about clothing availability. Chattaraman and Rudd (2006) reviewed multiple studies which assessed preferences and perceptions in styling attributes and reported a number of papers using Likert scales, Semantic Differential scales, and one using a combination of Likert and Rating scales (Feather, Ford & Herr, 1996 cited in Chattaraman & Rudd, 2006). When analysing the data, Likert scales cannot be directly compared to VAS’s, due to Likert scales typically being descriptive (for example, strongly disagree, disagree, neither agree nor disagree, agree and strongly agree) whereas a VAS is a numerical value. This is an important consideration for measuring aesthetics within a bra prescription session as it is vital that an overall decision can be made to prescribe an appropriate bra. Therefore, comparison between KPI’s is necessary and it is more appropriate to use a rating scale such as the VAS, for comparability with the subjective measures of comfort and support. Within the results of the focus group and interviews (Chapter Two), there were five higher order themes for the general dimension of aesthetics.
These higher order themes can be used to collect subjective measurements of aesthetics; bra style, bra shape, the look of the bra, breast coverage and modesty, and how the bra makes you feel.

Niemczyk, Arnold and Wang (2017) reported how important a well-designed bra style was due to the variation in women’s breast size and shape. There are many different bra styles ("Bra style guide," 2014) and Chapter Two established that preferences vary making it important that the patients within the intervention study have an opportunity to provide their subjective ratings on style. Tsarenko and Strizhakova (2015b) report that bra style is one of the key factors assessed by women in retail changing rooms when receiving a bra fitting.

Shape is a key indicator of form and leads to the judgement of the aesthetic quality of a garment (Morganosky & Postlewaite (1989) cited in Chattaraman & Rudd, 2006). The importance of the shape the bra gives the female form has also been presented in the literature as it can positively alter body image (Tsarenko & Strizhakova, 2015), the bra does this by encapsulating the breast tissues into each cup, moulding it into a more aesthetic and feminine shape (Krenzer, Starr, & Branson, 2005). A poor breast shape can be associated with low self-esteem (Frederick, Peplau, & Lever, 2008). Bra shape was also rated by participants within the study on bra fitting for middle-aged women with larger breasts by Filipe, Carvalho, Montagna and Freire (2015) as it was identified as an important performance variable (Risius, 2012). It was also an important factor for women suffering from breast cancer, whose breast shape may have been altered by surgery (Gho, Munro, Jones, & Steele, 2014). It was a recommendation that exercise bras for women with cancer take into account the shape it gives the breasts (Gho et al., 2014). As with style, patients will be asked to rate the shape of the bras that have been selected.

Bowles, Steele and Munro (2012) found that participants were deterred from wearing a sports bra due to the look of the bra. How a bra looks is also considered within the design process, with sport bra design literature considering the look of the bra (to give a more flattering appearance) in the design of its prototype (Krenzer et al., 2005). For the intervention, it is important that the participants adhere to wearing the bra they are prescribed, therefore it is important that the prescribed bra is not a deterrent. Therefore, participants will also be asked to rate the look of each of the selected bras within the bra intervention study.

Research has found a correlation between body size and the want for greater body coverage (Chattaraman & Rudd, 2006). It could be assumed that women with a larger bra size may have a greater need for breast coverage from her bra. It is therefore important that
the amount of breast coverage the bra gives is assessed by the participants to ensure it meets their requirements and preferences.

How a woman feels can be affected by her underwear and it is reported that this contributes to different aspects of a woman’s self-identity (Tsaousi & Brewis, 2013). The way underwear makes women feel was explored by Tsaousi and Brewis (2013). They identified that women felt that the term “lingerie” only applied to underwear that made them feel special and that women have underwear to suit their different identities; with bras for work differing from bras for intimate activities. Fifty-five percent of adolescent females reported that feeling good was a very important aesthetic characteristic (De Klerk & Tselepis, 2007). The females also expected to feel good in their clothes (De Klerk & Tselepis, 2007). Participants in this thesis will therefore be asked how each bra makes them feel (Figure 4.8).

![Figure 4.8: Visual Analogue Scales for measuring aesthetics within the bra prescription session](image)

These measurements will be taken at the beginning of the bra prescription session. In a standard bra shopping experience, these factors typically will be considered by a woman prior to purchase or immediately post-purchase when tried on at home. Tsarenko and Strizhakova (2015b) reported that many of the aesthetic features of bras are typically assessed during the bra fitting process in stores, therefore this confirms the timing of this measurement.

### 4.1.4 Fit

Poorly fitting bras are a problem for all women, as they can cause breast pain, but also back, neck and shoulder pain (McGhee & Steele, 2010b). Additionally, poorly fitting bras can cause poor posture, shoulder grooving and neural tract problems leading to numbness in the fingers (McGhee & Steele, 2010b). The fit of the bra is typically assessed objectively in stores using the traditional tape measure method (McGhee & Steele, 2006; White & Scurr, 2012).
Development of the bra prescription session

The encouraged method is to assess fit objectively using the five-point best fit method (McGhee & Steele, 2010b; White & Scurr, 2012). This method advocates the use of a visual and physical assessment of whether a bra fits correctly over five key points on the bra (under band, straps, centrepiece, underwire and cups). The variations in shape and styles of bra, alongside the differences in breast and body shapes, make this method of fitting bras more appropriate than using a tape measure. This method will be used in the bra prescription session and the steps taken to assess the fit of each bra are detailed below (Figure 4.9).

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Loosen the bra straps prior to the participant putting the bra on</td>
<td>N/A</td>
</tr>
<tr>
<td>2</td>
<td>Ask the participant to put the bra on, adjusting their breast tissue and pulling the bra on the loosest setting</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| 3    | Check the firmness of the under band. The under band should be able to be pulled away from the body by approximately two inches but should feel firm when pulled. | Meets criteria: Continue to step 4  
Does not meet criteria: adjust the under band size (increase the size if the under band is tighter than two inches and decrease if the under band is looser than two inches). |
| 4    | Ask the participant to lift their arms to identify if the under band moves and to check it is level all the way round the body. | Meets criteria: Continue to step 5  
Does not meet criteria: adjust straps to see if this can level the under band. If this does not help and the bra still moves, adjust the under band size (decrease if the under band moves). The under band may also not be level if there is breast tissue under the under wire or if the cup size is too small. These should be checked at this point as well. |
| 5    | Check the firmness of the bra straps. The straps should be able to be pulled away from the body approximately one inch. | Meets criteria: Continue to step 6  
Does not meet criteria: Adjust straps to appropriate tightness |
| 6    | Look at the bra under wire. The under wire should not sit on any breast tissue. There should also not be a gap between the under wire and the infra-mammary fold. At the same time look at the centre front of the bra, this should be sat against the chest wall but not on any breast tissue. | Meets criteria: Continue to step 7  
Does not meet criteria: Adjust the cup size. Increase the cup size if the wire is sat on breast tissue. Decrease the cup size if there is a gap between the underwire and the inframammary fold. |
| 7    | Check the fit of the bra cups. The bra cups should not wrinkle, gape and no breast tissue should bulge over the outside of the cup. | Meets criteria: The bra meets the best-fit criteria  
Does not meet criteria: Adjust the cup size. Decrease the cup size if the bra is wrinkling or gaping. Increase the cup size if the breast tissue is bulging over the bra. |

Figure 4.9: Steps taken to objectively fit each bra to the participant in the bra prescription session based on the five-point best fit method (White & Scurr, 2012).

Using this method will ensure participants are only tested in, and only prescribed a bra which fits them. It is acknowledged that some bra shapes may not fit all participants therefore, there may be instances where a good bra fit cannot be achieved in a particular bra. This means some participants may not be tested in all six bra styles established in the bra selection chapter (Chapter Three).

McGhee and Steele (2010b) reported that women did not typically take up bra fitting services, either due to a lack of services being available or choosing not to use them. Additionally, 20% of an active population (Brown et al., 2015), had never had a professional bra fitting. This suggests that women are subjectively assessing bra fit themselves,
therefore, a subjective assessment of bra fit by the participant (following an objective fit by the researcher) is also important. The VAS will be used for assessing subjective fit to align with the subjective measures of comfort, support and aesthetics. Subjective measures of bra fit have not been assessed within the literature previously despite many women choosing not to take up professional bra fitting services, therefore choosing their own bra size.

There needs to be careful consideration of how subjective bra fit affects the bra prescription, as most women are not able to accurately assess the fit of their own bra (Greenbaum et al., 2003). To counteract this, a subjective fit assessment will be completed by the participant after the objective fit is completed and a well-fitting bra is found. This will ensure that every bra that the participants assess for fit meets the best fit criteria. Participants will rate their bra fit as their perception may not be the same as the researcher. This will also allow for the participant to compare the fit of each of the bras. This measurement will also be completed using a 100 mm VAS (Figure 4.10).

Figure 4.10: Visual Analogue Scales for measuring fit within the bra prescription session

4.2 Data analysis considerations for subjective measurements

The VAS data will be collected using a VAS application (Visual Analogue Scale, Developer; Kyrill Schwegler). Participants will be able to mark any point along the horizontal scale which would then be exported into a spreadsheet as a number from 0 to 100. To maintain conformity, the positive descriptors are always on the left and negative descriptors on the right. Electronic VAS have previously been assessed for reliability and validity. Jamison et al. (2001) identified that electronic VAS are comparable to paper VAS. There are benefits for using electronic VAS over paper; minimised risk of ambiguous markings, less measurement error, measurements can be time and date stamped and there is minimal chance to look at previous VAS answers (Jamison et al., 2001; Lane, Heddle, Arnold, & Walker, 2006). Additionally, electronic VAS can save time during data handling and processing as it removes the need to manually measure each scale (Lane et al., 2006). A percentage closer to 100 indicates greater ROM, velocity and acceleration reduction for objective support, whereas on the VAS a value closer to 100 is a more negative response. To be able to compare these scores the VAS scores will be reversed after measurement.
4.3 Methods for weighting the Key Performance Indicators

Weightings for each of the KPI’s have been established using the percentage of reported mentions for each variable within Chapter Two (Figure 4.11).

Figure 4.11: Method used to weight each of the bras across the four KPI’s of comfort, support, aesthetics and fit.

Once all bras have been analysed, a ranking will be applied. Previous research has used this method to assess the satisfaction and expectations relating to clothing and purchasing behaviours (De Klerk & Tselepis, 2007; Kawabata & Rabolt, 1999); these studies used surveys to determine the importance of different clothing factors (such as durability and brand), participants then rated these factors on Likert type scales (De Klerk & Tselepis, 2007; Kawabata & Rabolt, 1999) averages of these results were taken and a ranking applied (Kawabata & Rabolt, 1999). Once the bras have been ranked, the bra ranked top will be prescribed to the participant.

4.4 Conclusions

This chapter has reviewed and identified the methods needed to assess each KPI within the bra prescription session (Table 4.1).
Table 4.1: Objective and subjective methods of assessing each KPI

<table>
<thead>
<tr>
<th>Key Performance Indicator</th>
<th>Objective Measure</th>
<th>Subjective Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort</td>
<td>N/A</td>
<td>VAS</td>
</tr>
<tr>
<td>Support</td>
<td>Optoelectronic cameras to measure reductions in breast movement, velocity and acceleration</td>
<td>VAS</td>
</tr>
<tr>
<td>Aesthetics</td>
<td>N/A</td>
<td>VAS</td>
</tr>
<tr>
<td>Fit</td>
<td>Best fit method</td>
<td>VAS</td>
</tr>
</tbody>
</table>

It is important to also reflect on the interaction between the KPI's. For example, a poor bra fit can lead to feeling uncomfortable (Chapter Two), and consequently this can affect whether a woman feels good in it (aesthetics) (Tsaousi & Brewis, 2013). The shape of the bra (aesthetics) is also an indicator of a good fit. A poorly fitting bra can affect the level of support it provides. Compressive bras may be more supportive (McGhee & Steele, 2010a), but they may negatively affect the aesthetics (by flattening the shape of the breasts) and comfort of the bra (Chapter Two).

This chapter also identified the practical considerations with assessing the KPI's and prescribing bras to the participants (Figure 4.12).
Development of the bra prescription session

Figure 4.12: The process and procedures each patient will follow for all six bras, plus their own everyday bra.

Following the prescription session each patient’s data will be analysed using the methods described in this chapter and then the weighting method described in section 4.3 will be applied and the patient will have the top rated bra prescribed to them.

This chapter has ensured that the method of prescribing bras is established using a combination of well-established methods and piloting. Craig, Dieppe, Macintyre, Mitchie et al. (2008) recommend that a systematic approach is used when developing an intervention so that the unknowns or uncertainties can be addressed through piloting. Having established the methods for prescribing the bras, the next chapter will determine the methods for the bra intervention period following the bra prescription. This is the final step in the development phase of the 2008 guidelines produced by the MRC (Craig, Dieppe, Macintyre, Michie, et al., 2008).
Chapter Five: The development of the bra intervention

5.1 Introduction

This chapter is the final stage within the development phase of this programme of work (Craig, Dieppe, Macintyre, Michie, et al., 2008). This chapter focuses on the design of the bra intervention itself; determining the trial design, defining the outcome measures and obtaining ethical approval.

As discussed in the review of literature (Chapter One), the RCT is considered the gold standard of trials designs as it minimises selection bias and systematic error (Craig, Dieppe, Macintyre, Mitchie, et al., 2008; Levati et al., 2016). As this is a new intervention, it is appropriate for a RCT to be conducted (Craig, Dieppe, Macintyre, Mitchie, et al., 2008). Currently the bra is recommended within the literature as a method for reducing breast pain but there has yet to be an evidence-based RCT to confirm the findings of previous research (Hadi, 2000; Wilson & Sellwood, 1976).

An RCT typically has two groups; a control group and a treatment group (Kendall, 2003). Both groups are typically highly controlled to ensure that results are due to the intervention and not variations across participants. To ensure the RCT within this thesis is highly controlled, all patients will be recruited from the New Patient Breast Clinic at the Queen Alexandra (QA) Hospital in Portsmouth.

There are a number of additional factors which are important to the design of an RCT, these include; randomisation, the length of the monitoring period, the outcome measures, sample size estimation and blinding.

5.1.1 Aims

The aims of this chapter are to;

1. Determine the procedures for randomising participants
2. Define the length of the monitoring period and ensure this fits in with current clinical treatment for benign breast pain
3. Decide on the outcome measures to assess the effectiveness of a prescribed bra at reducing breast pain and improving QoL
4. Determine the sample size
5. Determine the procedures for blinding the participants and clinician’s to group allocation

5.2 Randomisation

There are a number of methods available to randomise patients into either the treatment or control group; simple, blocked, stratified and adaptive (Beller, Gebski, & Keech, 2002). Simple randomisation is a technique where one sequence of random numbers are
Bra intervention development

generated (Beller et al., 2002). Blocked randomisation uses “blocks” to maintain a balance of patients assigned to the two groups and is useful for smaller studies (Beller et al., 2002). Within each block, an even number of people are allocated to the treatment group and control group (Beller et al., 2002). The order of the allocation within each block is random (Beller et al., 2002). Stratified randomisation is more restrictive (Beller et al., 2002); it uses blocked randomisation but the randomisation lists are generated for each group of prognostic factors or characteristics of the patients (Beller et al., 2002). This ensures there is balance across the prognostic factors or characteristics within the groups (Beller et al., 2002). Adaptive randomisation is dynamic and randomly allocates each new patient based on the patients who have already been allocated to a group, to balance characteristics of patients ‘live’ (Beller et al., 2002).

The RCT in this programme of work used an allocation ratio of 1:1 and was a parallel design with two groups; a standard care group (acting as the control) and a bra prescription group (who received the intervention). This study used a blocked randomisation design (random permuted blocks of two) to assign participants to the standard care or bra prescription group as it was the most appropriate. The randomisation table was generated using www.randomization.com prior to the start of the study recruitment.

5.3 Monitoring Period

The length of the monitoring period once the bra has been prescribed is important. The key studies which have previously assessed bras for their effectiveness at reducing breast pain have supplied bras to patients for a period of between six and 18 months (the bra was the only treatment), with follow-ups every three months (Wilson & Sellwood, 1976) or for a period of 12 weeks (Hadi, 2000). In Hadi (2000) one group received a sports bra and the other group received 200mg/day of Danazol. Long term follow-up may be needed to determine whether any short-term changes continue, although these are uncommon (Craig, Dieppe, Macintyre, Mitchie, et al., 2008).

The initial proposal was to complete the RCT with a three month period to assess baseline breast pain, then the treatment would be applied, and then there would be a three month monitoring period where the patients were followed up in line with a previous bra intervention study (Hadi, 2000). Mansel (1994) suggested that to identify the type of breast pain, a patient should keep a breast pain diary for at least two months. A diary was therefore developed and assessed for reliability and validity (Appendix E and G). To assess breast pain over the monitoring period, a survey was developed and assessed for reliability (Appendix E, F, I). The diary aspect of Appendix E has now been published (Sharland, Burbage, & Wakefield-Scurr, 2017). However, a three month intervention and three month
follow up the bra intervention was deemed unfeasible by the Consultant Nurse Specialist due to the timing of the contact with patients.

Patients with breast pain who attend the clinic have been referred by their GP. The clinician then sees the patient and takes a course of action (further examinations and tests if needed) and standard care is provided if no additional breast issues are identified. Patients are advised by some clinicians to be re-referred by their GP after eight weeks if there has been no change. This had an effect on the ability to conduct research that assessed baseline breast pain to identify the type of breast pain, which the original protocol proposed. This is because patients would start standard care treatment immediately following their consultation, potentially causing changes to the breast pain they were experiencing.

Standard care consists of; a recommendation to wear a well-fitting bra that has been professionally fitted (however, no advice was given on where such services may be accessed), to apply topical ibuprofen to the painful area of the breast (not provided) and to refer to a breast pain leaflet (developed by Breast Cancer Care (“Breast pain,” 2010)). Additionally, a time constraint was introduced for the monitoring period, as patients could be re-seen eight weeks after their initial visit. Consequently, the monitoring period was limited to eight weeks with follow-ups at four and eight weeks as a longer intervention at this stage could lead to confounding variables being introduced as further investigations into the patient’s breast pain may be conducted.

5.4 Outcome measures

Chronic pain (for example breast pain) should be measured multi-dimensionally as this will show the intensity of the pain and other sensory related factors such as pattern, timing and location (Breivik et al., 2008). The types of questions which could be asked are; “Where is the pain?” or “Describe the pain (e.g. burning, aching, stabbing, shooting, throbbing etc.)” (Breivik et al., 2008). These questions can gain an understanding of the sensation, but ultimately it is the patient’s perception of that sensation that is being measured. The variability of pain perception contributes highly to difficulties in pain measurement (Melzack, 1996). The answers provided during perceptual measurement is also reliant on how the question is interpreted (Krosnick, 1999).

Without a valid multidimensional measure/s of pain prior to the start of treatment; reductions in pain perception may not be captured. Advances in technology have seen neurological imaging suggested to objectively measure pain sensation or intensity, as the neurological patterns of the brain could visually show the effectiveness of certain treatments (Wager et al., 2013). Neurological imaging has been suggested as a potential replacement for the self-reporting method (Robinson, Staud, & Price, 2013). Self-reporting methods are sensitive to
the treatment of pain but as of yet the sensitivity of neuroimaging is unknown (Robinson et al., 2013). Neurological imaging of pain is also expensive and limited to clinical use and the assumption that neuroimaging the brain is more reliable and valid than self-reporting has yet to be experimentally assessed, therefore, self-reporting methods are recommended as the most appropriate measure of pain (Robinson et al., 2013).

A more recent meta-analysis by Cowen, Stasiowska, Laycock and Bantel (2015) assessed a range of methods to objectively measure pain. These methods included; autonomic nervous system markers such as heart rate variability, bio-potential markers such as spinal polysynaptic withdrawal reflex, neuroimaging and biological biomarkers such as stress hormonal and metabolic changes (Cowen et al., 2015). Developing these objective tools will enable clinicians to understand the pain being experienced by those unable to self-report (Cowen et al., 2015). The paper concluded that the methods have potential, but there is a lack of evidence to support their current use (Cowen et al., 2015). This supports the continued use of the self-reporting methods in this thesis.

5.4.1 Considerations

5.4.1.1 Perceived versus measured change

One consideration is whether to conclude a successful outcome of an intervention by the patients perceived change in their pain or a measured change in pain. Previous studies have assessed patient’s opinion of their improvement as well as statistical change when patients have reported a numerical value for pain intensity on a rating scale for example. There is debate regarding whether it is meaningful to having statistical outcomes (of breast pain) as the primary outcome when the patient’s opinion may contradict with this. Pain can only be perceived by the patient, it may only be measured by self-perception, and no one else can assess whether that patient is experiencing pain (A. Sen, 2002). Therefore, the bra intervention will not be successful if a statistically significant reduction in breast pain occurs but the patient does not feel any improvement in their condition. Within a clinical environment, not considering the patient’s perception of their pain could be problematic as this may lead to re-referrals and complaints. As a consequence of this, and because no objective pain measure is available, the primary outcome for this study should be a patient reported outcome, supported by statistics. The decision to make the primary outcome measure a patient reported one, supports the relativistic constructivist ontology from section 1.1.9. However, these outcomes will be supported by secondary outcome measures, yet these will also be based on subjective measures.

Younger et al. (2009) reports that for a treatment to be considered effective, it has to have clinical and statistical significance, with clinical significance showing whether an effect is
important and a statistical significance showing whether an effect is real. Todd (1996) reported that statistical analyses are necessary for interventions, however, they do not provide sufficient evidence to deem one intervention better than another. For the bra intervention, statistical significance was used to support the patient reported outcomes, which allowed the intervention to be determined a success or not, however, clinical significance was also presented.

5.4.1.2 Pain and its relationship to quality of life

Quality of life is an individual’s perception of how they are functioning in life and their well-being (Niv & Kreitler, 2001). In particular, Health Related QoL (known as HR-QoL) focuses on a health issue (for example, breast pain) and how this has affected QoL (Niv & Kreitler, 2001). Although pain is not completely synonymous with QoL, treating pain often has a positive effect (Niv & Kreitler, 2001).

Quality of life is often assessed in breast health studies (Ader & Shriver, 1997; Agbenorku, 2013; Bicego et al., 2008; Bloom, Stewart, Chang, & Banks, 2004; Carmichael et al., 2006; Khan & Apkarian, 2002a; Rogliani, Gentile, Labardi, Donfrancesco, & Cervelli, 2009; Scurr et al., 2014; Shimozuma, Ganz, Petersen, & Hirji, 1999; Sukanya et al., 2016; Thicke et al., 2011). These studies cover a wide range of topics within breast health including breast pain (cyclical and non-cyclical), breast surgery (reduction and enlargements), breast cancer, the effects of treatments (pharmacological and non-pharmacological, and holistic therapies), and also studies investigating the demographics of certain populations.

The Breast Pain Questionnaire was developed by Khan and Apkarian (2002a, 2002b). This questionnaire included a measurement of QoL which covered three aspects; sexual activity, ability to sleep and ability to work. This questionnaire was used within the study by Carmichael, Bashayan and Nightingale (2006) (assessing women attending a UK clinic for breast pain) and found sexual activity was affected for 30%, sleep was affected in 43%, and work was affected in 28%. A similar study (Scurr et al., 2014) investigating the prevalence of breast pain in the UK general population found their breast pain affected; their sexual activity (41%), their sleep (35%) and their ability to work (5%). This demonstrates that breast pain can have a negative impact on QoL. Sexual activity, sleep and work do not cover all aspects of QoL and further investigation into the effect of breast pain on QoL should be completed. Patients with breast pain have greater anxiety, depression and somatisation (Colegrave et al., 2001) therefore it was also important to assess how breast pain affects mental QoL as well as physical aspects.
5.4.2 Patient’s Global Impression of Change

The Patient Global Impression of Change (PGIC) scale is widely used and referenced within pain assessment (Amirfeyz, Pentlow, Foote, & Leslie, 2009; Farrar, Young, LaMoreaux, Werth, & Poole, 2001; Rosenstock, Tuchman, Lamoreaux, & Sharma, 2004; Serpell, 2002; Strand, Ljunggren, Bogen, Ask, & Johnsen, 2008; Younger et al., 2009) and is a method where patients can self-report improvements in their pain. The PGIC is a validated 7 point scale where; 1=very much improved; 2=much improved; 3=minimally improved; 4=no change; 5=minimally worse; 6=much worse; 7=very much worse (Rosenstock et al., 2004). The PGIC is typically used to assess pain at the end of an intervention based on the change from the start of the intervention (Rosenstock et al., 2004).

A clinically significant result is typically suggested to be a rating that the patient’s condition is “much improved” or “very much improved” (Farrar et al., 2001). The change form “much improved” to “very much improved” is regarded equal to a clinically significant reduction of 2 points on a Numerical Rating Scale (Younger et al., 2009). To statistically analyse this scale, a Fishers exact test was used to compare the proportions of patients meeting the clinical significance criteria compared to those who did not.

5.4.3 Breast Pain

The two main scales available for measuring subjective pain are the VAS and the Numerical Rating Scale (NRS). There is research that suggests that VAS can be difficult for respondents to understand, with age having a negative effect on the ability of the respondents to complete the VAS (Kremer et al., 1981, cited in Williamson & Hoggart, 2005). The VAS is favoured less by respondents, they find it harder to use and consequently this scale has a higher failure rate than the NRS (Williamson & Hoggart, 2005). Conversely, there is no evidence to suggest older adults cannot use the NRS (Williamson & Hoggart, 2005). Additionally the NRS is also suggested to collect better data from respondents who are illiterate (Ferraz et al. 1990 cited in Ho, Spence, & Murphy, 1996).

Participants will answer follow up questions relating to their breast pain from their home setting. This is to ensure that participants feel comfortable, are able to give an honest answer and to know that location will not influence the answers they provide. This does mean however, that patients must be able to understand the questions they have been asked. The NRS is the most appropriate scale in this instance, as currently, the ages and literacy levels of the participants are unknown and the participants will be required to complete the scales without a researcher present.

The NRS has been found to correlate with the VAS (Bijur, Silver, & Gallagher, 2001; Downie et al., 1978) and have high levels of agreement with the VAS (Bijur et al., 2001). DeLoach,
Higgins, Caplan, and Stiff (1998) however found NRS data correlated with VAS, but there were low levels of agreement between the two. The NRS has also been used to measure breast pain in breast biomechanics (Mason et al., 1999; Milligan et al., 2014; Scurr et al., 2010), breast health (Armstrong, Ried, Sali, & McLaughlin, 2013) and breast pain (Muralidhar, Keerthi, Akuri, & Dongari, 2016) studies. Due to its wide use within the clinical setting, understanding by a wide range of respondents, use within previous research, and that it correlates with the VAS the NRS was the scale used to measure breast pain within this thesis.

### 5.4.4 Quality of Life

There are many QoL surveys available, but not all are appropriate for use in a bra intervention. The SF-36 is a QoL survey which measures both physical and mental components of QoL. It is the most used survey to measure HR QoL (Coons, Rao, Keininger, & Hays, 2000). Nine aspects are measured; bodily pain, physical functioning, vitality, role limitations due to physical functioning, general health perceptions, social functioning, role limitations due to emotional problems, mental health and health transition (Rand Corporation, n.d.). These components can be grouped into; the Physical Component Summary (PCS) and the Mental Component Summary (MCS) (Ware, Jr. & Kosinski, 2001). The burden on respondents is minimal, as it takes around seven to 10 minutes to complete (Coons et al., 2000).

Brazier et al. (1992) compared the SF-36 to the Nottingham Health Profile survey. This was one of the first studies assessing the reliability and validity on a general British population. The SF-36 was found to have test-retest reliability, internal consistency and validity. Respondents were less likely to leave missing values on the SF-36 compared to the Nottingham Health Profile, and this study found respondents only took five minutes to complete it. The Nottingham Health Profile has been found to not provide a representative picture of the general population (Brazier et al., 1992). It is therefore unsuitable for use in the bra intervention. It is acknowledged that some participants may experience severe levels of breast pain that could be identified by the Nottingham Health Profile survey, yet the SF-36 is more appropriate for minor conditions. One potential problem with the SF-36 is its reliability/effectiveness in the older generation as there were greater volumes of missing data compared to younger participants (Brazier et al., 1992).

The SF-36 was initially developed and used for the Medical Outcomes Study (Rand Corporation, n.d.), but it has subsequently been used in breast health studies. Klassen, Fitzpatrick, Jenkinson and Goodacre (1996) used the SF-36 to assess patients undergoing breast reduction surgery. The SF-36 was used prior to and after the surgery to identify the
benefits of breast reduction surgery on health status. Similarly, Rogliani, Gentile, Labardi, Donfrancesco, and Cervelli (2009) used the SF-36 on breast reduction surgery patients, to assess the physical and psychological improvements of this surgery on patients. Significant improvements in seven out of eight scales were identified when comparing pre- and post-operative QoL. Additionally, a recent study has been published using the SF-36 in an intervention study assessing the effectiveness of exercise on breast pain (Genç et al., 2017) which identified some significant improvements within the control group, and within the exercise group. In the between group comparison, the exercise group saw a significantly greater improvement over the control group in the role physical variable.

Due to its wide use within the literature and the ease of completion, the SF-36 (Appendix D) was used within this thesis as the QoL measure. The nine components were assessed individually, and the PCS and MCS was assessed. A statistically significant improvement in QoL was assessed by completing the SF-36 pre and post intervention, with additional points of measurement during the monitoring periods to show progress of the intervention. A clinically significant improvement in QoL measured using the SF-36 has been reported as a ≥2.5 point’s improvement in the PCS and MCS scores or a ≥5 point’s improvement in individual SF-36 domain scores.

5.4.5 Other Considerations

5.4.5.1 Adherence to treatments

Compliance is defined in medical literature as ‘the extent to which a patient’s actual history of drug administration corresponds to the prescribed regimen’ (Urquhart, 1996). This definition can be applied to non-medical treatments such as a bra as it is important to assess whether participants in the bra intervention adhere to wearing their prescribed bra. The terms adherence, concordance and compliance have been used interchangeably, but adherence has more positive connotations and therefore will be used within this thesis (Vermeire & Hearnshaw, 2001). Adherence to a treatment is a complex problem and high adherence cannot be assumed (Vermeire & Hearnshaw, 2001).

Adherence can be measured directly and indirectly. With a bra intervention indirect measurements are most appropriate, as a direct measurement would involve the researcher checking daily that participants are wearing their prescribed bra. The indirect method is more commonly used and is more acceptable (Vermeire & Hearnshaw, 2001). Self-reporting is a method of indirectly measuring adherence using interviews or surveys (Vermeire & Hearnshaw, 2001). It is however, more likely with indirect methods, that participants may alter their responses to seem more compliant. Consequently, this can lead to adherence being overestimated (Vermeire & Hearnshaw, 2001).
Adherence was one of the uncertainties with the bra intervention as it was unknown how participants would comply with the study. Compliance can be improved by improving the “doctor-patient” relationship (in the bra intervention it was the researcher-patient relationship) (Vermeire & Hearnshaw, 2001). This indicates that frequent contact with the participants may help to build a rapport and increase the likelihood of adherence.

It was therefore important that adherence to the bra intervention was monitored regularly, using a self-reporting method, as this may have had a large effect on the outcome of the study. Within this thesis, patients completed the outcome measures (PGIC, NRS, SF-36) from their homes, therefore, the appropriate methods of contact were either via phone call or email depending on their preference. Fifty percent adherence or more was considered high, as the average adherence for medication based research is 50% (Haynes, McDonald, & Garg, 2002).

5.5 Sample size

To ensure the recommended power of 0.80 was achieved (Cohen, 1988), a priori sample size estimation was calculated. G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) is a tool that has been developed to calculate sample size estimations. Sample size calculations are designed to ensure that significant results occur when there “truly is one” (Eng, 2003).

Sample size was estimated using G*Power (Faul et al., 2007). Sample size was calculated using data from a previous survey which used the PGIC in a double-blinded study with a placebo control for Gabapentin (pharmacological treatment) used to aid neuropathic pain syndromes (Serpell, 2002) because no data exists specific in the area of this programme of research. This compared the number of participants who rated their condition as “much improved” or “very much improved” within the two groups (34% for the intervention group and 16% for the placebo group). A test for comparing the difference between two independent proportions was used to calculate sample size, resulting in a total sample of 180 participants (split 90 in the prescription group and 90 in the standard care group) to get a power of 0.80 (Cohen, 1988).

5.6 Blinding

Blinding is designed to minimise bias that occurs from expectations of a trial (Day & Altman, 2000). There are different aspects of a study that can be subject to blinding, including; allocation concealment (whether a patient is allocated to the control or treatment group) which minimises selection bias (Day & Altman, 2000), and/or a treatment (whether a patient receives a treatment or a placebo).

Allocation concealment in this programme of work will be completed by the researcher involved in the study due to no availability of external help to complete this. Therefore, the
next appropriate and feasible method of allocation concealment is to design study packs with numbered opaque envelopes (Altman & Schulz, 2001; Kendall, 2003). The envelopes are then opened sequentially once the patient is recruited into the study (Altman & Schulz, 2001; Kendall, 2003).

Blinding to treatment is reported to be important for studies where the outcome measures are subjective e.g. pain (Day & Altman, 2000). There are situations where blinding is not possible (Day & Altman, 2000). For the bra intervention, treatment blinding is not possible, as unlike a drug trial, a bra is a visible treatment and patients will know if they have their own bra (control) or a new prescribed bra (treatment). This means ultimately patients, clinicians and researchers are aware of the treatment they have been provided.

Study packs were made for 200 potential participants (100 for the bra prescription group and 100 for the standard care group); 180 participants were recommended for the sample size (90/90), plus 20 extra study packs to accommodate for drop outs. Study packs included a participant information sheet, a contact sheet, and the baseline surveys plus, an exercise and health history form for those in the bra prescription group. Study packs were sealed by the main researcher over two weeks prior to the study start and not opened until the participant had been informed about the full study procedures and consented to participate. Each study pack was assigned a participant number which then stayed with the recruited participant throughout the study. This allowed surveys to be anonymous from the start of the study.

Participants were blinded to the group allocation prior to consent and their group assignment will only be revealed to them post-consent. This is to minimise any selection bias (Altman & Schulz, 2001; Day & Altman, 2000), and means that the patient has to agree to be part of either group before participating, otherwise they will not be deemed eligible to participate. Clinicians in the Breast Services Department will also be blinded to the study allocation to minimise the effect of any bias when discussing the study with the patients.

5.7 **Obtaining ethical approval**

The recruitment time available for this study was limited due to a lengthy protocol development and ethics process which delayed the project start. As discussed in section 5.3 the protocol was revised following meetings with the clinical nurse specialist. Any member of the study team who would come into contact with the patients would have to obtain a research passport. This took some time to establish as Disclosure and Barring checks had to be completed alongside Good Clinical Practice training and an Occupational Health check (which included some vaccinations).
Figure 5.1: Process to obtain ethical approval for the randomised controlled trial.

A favourable ethical opinion was given on the study through the NHS Research Ethics committee (Nottingham1). The trial was also registered on the clinicaltrials.gov website for the duration of the study.

5.8 Summary

This chapter has; identified the procedures for randomising the participants (blocked randomisation with permuted blocks of two), determined the length of the intervention (eight weeks with a four week follow-up), decided the outcome measures (PGIC, NRS, SF-36), determined the sample size ($180 = 90/90$) and determined that patients and clinicians will be blinded to group allocation to minimise selection bias.

So far this programme of research has identified the bra preferences and concerns of women who are experiencing breast pain and identified that women are interested in the concept of a bra prescription service (Chapter Two), developed a novel method of selecting bras using a criteria and identified the bras most appropriate for use within the bra
intervention (Chapter Three), established the methods and analyses that will be used to prescribe bras to the patients using previously established methods and pilot work (Chapter Four) and then developed the methods for the bra intervention itself (Chapter Five). The next stage for this thesis is to run a feasibility/pilot study (Figure 5.2) of the bra intervention with patients who are experiencing breast pain and have larger breasts.

**Figure 5.2:** Medical Research Council 2008 guidelines for developing an complex intervention. The next stage of this thesis will explore the feasibility of the study, by piloting the intervention.
6 Chapter Six: A randomised controlled trial to assess the efficacy of the bra intervention versus standard care on breast pain and quality of life in women with larger breasts

6.1 Introduction

This thesis has now developed the method for prescribing the bra and the methods for running the bra intervention. As previous research has identified that bras can reduce breast pain (despite not being RCT’s) (Hadi, 2000; Wilson & Sellwood, 1976) it is likely that the bra prescription group will see a greater improvement in their condition and a reduction in their breast pain following the prescription of the bra than the standard care group (who only get a recommendation to get a professionally fitted bra. This is because the traditional method of bra fitting (often still used in stores), is not accurately and results in errors of up to four cup sizes when compared to the five point best fit method (White & Scurr, 2012). Also, research has identified that women find it difficult to purchase appropriately fitting bras even after receiving a bra fitting (Woollett et al., 2012). As breast pain is negatively associated with QoL (Carmichael et al., 2006; Scurr et al., 2014), it is also expected that prescribing a bra to patients in the bra prescription group will have a greater effect on QoL than the standard care recommendations.

As this study is a pilot RCT, it is important to understand whether patients in both groups adhere to the treatments they have received. Adherence cannot be assumed and it is important to measure as it will demonstrate whether the patients follow the treatment they have been assigned (Vermeire & Hearnshaw, 2001). This will ultimately affect the outcome and will allow for the RCT to be evaluated appropriately. If the results show no effect on breast pain, data on whether patients have adhered to their treatment will allow for the conclusions to report whether no effect occurred due to poor adherence or if adherence was good, due to the treatment not being effective. Important feasibility aspects to assess are; the recruitment of patients, the retention of patients and to run a cost benefit analysis. Poor recruitment and retention of patients can affect the outcome of an intervention as statistical power could be lower than the recommended 0.80 (Cohen, 1988) and as a consequence there is a risk of concluding the intervention is ineffective due to a type two error (MacIntyre, 1991). It is also important that the cost effectiveness is assessed within the evaluation phase of the intervention (Craig, Dieppe, Macintyre, Michie, et al., 2008).

Aside from the outcome of the RCT and the feasibility aspects, it is important to understand how the bras chosen in Chapter Three performed within the bra prescription session. This ensures that there is some understanding of which bras were prescribed and why. It is important to understand how the bras chosen within Chapter Three fit the participants, as it...
may show a need to expand the criteria or it may show that six bras was enough to find each patient an appropriately fitting bra. The KPI's and weightings chosen for this cohort should also be evaluated to understand which bras were prescribed to each patient and how patients rated the bras themselves.

6.2   Aims

Therefore, the aims of the study were;

6.2.1   Primary Aim

To understand whether an individually prescribed bra (plus standard care) results in a higher number of patients reporting that their breast pain is "very much improved" or "much improved" on the PGIC scale compared to the patients receiving standard care alone.

6.2.2   Secondary Aims

1. To assess whether breast pain intensity and QoL is improved at four and/or eight weeks of the bra intervention (plus standard care) compared to the effect of standard care alone.
2. To assess the patient's adherence to the prescribed bra (bra prescription group) and the standard care (bra prescription group and standard care group).
3. To investigate the recruitment and retention of patients and to complete a cost-benefit analysis.

This Chapter will also present findings from the bra prescription session itself, therefore, the specific aims for this section of the chapter are:

4. To investigate the objective fit of the patient's bras; demonstrating which bras did not fit and were not tested.
5. To investigate how each of the bras tested ranked overall and across the four key performance indicators that were assessed (comfort, support, fit and aesthetics).

Additionally, this chapter will assess three feasibility factors to determine whether the intervention is feasible to implement within the NHS, therefore the final aim of this chapter is;

6.2.3   Hypotheses

\( H_1 \): A significantly higher percentage of participants within the prescription group will report their breast pain as "very much improved" or "much improved" compared to the standard care group at the four and/or eight week measurements.

\( H_2 \): Breast pain intensity will be significantly lower in the prescription group compared to the standard care group at the four and/or eight week measurements.
H₃: Breast pain intensity will be significantly lower within the prescription group at the four and/or eight week measurements compared to the measurement taken at baseline.

H₄: There will be no significant differences between breast pain intensity completed at four and/or eight weeks and compared to the measurement taken at baseline for the standard care group.

H₅: QoL will be significantly higher within the prescription group compared to the standard care group at the four and/or eight week measurements.

H₆: QoL will be significantly improved at the four and/or eight week measurements compared to QoL at baseline for the prescription group.

H₇: There will be no significant differences between the QoL completed at four and/or eight weeks and compared to the QoL at baseline for the standard care group.

6.3 Methods

6.3.1 Recruitment

Following NHS ethical approval (Chapter Five), patients were recruited at the QA Hospital in Portsmouth via the Breast Services Department. All potentially eligible patients attending the “New Patient Breast Clinic” were notified of the study by clinicians during their appointment and an initial assessment of eligibility was completed. Interested patients were then seen by the researcher who provided potential volunteers with a participant information sheet, a verbal description of the full study procedures and confirmed eligibility.

Recruitment, lasted six months, commencing on the 13th October 2015 and ended on the 14th April 2016. Each clinic (four per week) was approximately four hours in length and there were three weeks of additional clinics (an extra two hours per week). This equated to a minimum of 406 hours of clinic recruitment time when the researcher was present at the clinic and actively attempting to recruit patients.

6.3.2 Inclusion criteria

The final eligibility criteria are described below; these criteria were put in place six weeks after recruitment had begun. The original eligibility criteria included premenopausal females only and women who had never had any surgery to the breast. However, soon after recruitment began it was clear that recruitment would be slower than anticipated and the type of patients seen in clinic were different to that initially thought. It was also a concern that many women who attended the clinic had also had some form of breast surgery, whether recent or many years ago. This meant that some volunteers were missed due to their breast history, despite now experiencing unrelated breast pain. It was felt that controls
on both menopausal status and surgical criteria could be removed to as these women could potentially receive some benefit from improved breast support.

To participate, patients had to be aged 18 years and above and be experiencing benign breast pain of any severity. Patients were required to be able to speak and read English fluently, to ensure they could understand the study documents and procedures. Patients also had to be willing and able to provide informed consent to participate. Patients were required to have been seen within the New Patient Breast Clinic at the QA Hospital, as it enabled the study population to be cleared of any other breast issues (such as breast cancer and breast cysts) prior to their participation. It was also important that during the study period, that patients lived in the local area (covered by Portsmouth Hospitals Trust (PHT)) and were not planning to move out of this area during their participation in the study. Patients also had to self-report their bra size as between a 34 and 40 UK under band size and a between a DD to G UK cup size. Patients were included if they were below the DD cup size range (D cup size) but only if the patient reported they were in a bra that was too small and the clinician and/or researcher agreed with this. Patients were also required to be able to walk on a treadmill for up to two minutes unaided and be able to walk unaided up and down a small set of steps (assessed verbally by the clinicians or the researcher at QA Hospital). Patients were made aware of the procedures for both groups, and that they could be randomly allocated to either. Patients had to agree to comply with all the study procedures of either group to be eligible to participate.

Patients were not able to participate if they; were receiving any additional treatment that was not part of standard care, had had surgery to the breasts in the last year, were currently pregnant or had been pregnant or breast fed in the past year, were planning to undertake any activities or lifestyle changes which may affect their levels of breast pain e.g. trying for a baby, changing oral contraceptive, having breast surgery. Participant’s data were also excluded from the analysis if they did not complete both surveys at four or eight weeks (as at least one follow up survey was needed to be completed).

Finally, patients were withdrawn from the study if they did not fit into the testing bras once they arrived at the laboratory (n = 0), if their exercise and health history questionnaire was not signed off by the University of Portsmouth researcher, supervisors, or independent medical officer (n = 0), if their own bra performed better overall than the testing bras (n = 1), or if their circumstances changed and they then met some of the exclusion criteria (n = 0). As all the patients were volunteers, they were able to stop participating at any time.

### 6.3.3 Procedures

Upon providing consent, the researcher gave each participant a study envelope containing
details of which group they had been randomised to (section 5.2), along with the baseline surveys (Breast Pain Survey (Appendix I), SF-36 (Appendix D) and the exercise and health history questionnaire (bra prescription group only)) and a contact sheet (where participants were requested to leave contact details for the continuation of the study). Patients were then randomised into the standard care group (control) or the bra prescription group (intervention). Patients completed the contact sheet at the QA Hospital and were informed that if they did not return the surveys using the stamped addressed envelope after seven days, they would be contacted. Patients in the bra prescription group then liaised with the researcher to arrange a time to attend the University of Portsmouth for their bra prescription session. All patients, regardless of the group they were assigned to, were told that they must continue with any standard care provided by the clinicians at the clinic.

### 6.3.3.1 Standard Care Group

Patients in the standard care group received the standard care treatment that is provided at the QA Hospital as a control. Standard care is; a recommendation to get a professional bra fitting, to apply topical ibuprofen gel to the painful area and to refer to a breast pain leaflet provided by Breast Cancer Care (“Breast pain,” 2010) The care had not been adjusted for this study. Patients were then told they would be contacted in four and eight weeks’ to complete the next set of surveys. Once the eight week period was complete, each participant’s involvement in the study ended.

### 6.3.3.2 Bra Prescription Group

Additional to the standard care, patients in the bra prescription group attended the University of Portsmouth for the bra prescription session. Upon arrival to the laboratory, patients were given a full description of the session and consent was reaffirmed verbally. At the beginning of the session exclusion criteria were presented; that if they did not fit in any of the bras provided (despite self-reporting that they were within the bra size ranges required) or if their own bra received the highest ranking against the testing bras (their own bra would only be compared to the testing bras if it met the five point best fit criteria (White & Scurr, 2012)). The participant’s height in meters (using a stadiometer (Leicester Height Measure, Seca Ltd, UK)) and mass in kilograms (using weighing scales (Seca, Seca ltd, UK)) were then taken. The procedures for the bra prescription were established in Chapter Four (Figure 4.12).

Patients received the prescribed bra within a week of the session and, like the standard care group, were contacted four and eight weeks’ later to complete the next set of surveys. Patients were asked to wear the bra every day, and follow the manufacturers washing guidelines. Once the eight week period was complete, each patient’s involvement in the
study ended. In an attempt to improve adherence to the intervention, patients were given two of the prescribed bras to ensure they could wash one bra whilst the other is being worn.

6.3.3.3 Patient Pathway Chart

Below is the patient pathway chart which details the journey each patient took through the study (Figure 6.1).

![Patient Pathway Chart](image)

Figure 6.1: Patient Pathway Chart for patients recruited to both the bra prescription group and the standard care group within the bra intervention study

6.3.3.4 Four and eight week surveys

The Breast Pain Survey completed at four and eight weeks (Appendix J) consisted of the PGIC and an NRS. Use of the treatment for both groups (bra prescription plus standard care and standard care on its own) was not monitored directly, only retrospectively, where patients were questioned on their adherence in the form of yes and no questions with a
space for explanation if they did not complete the recommended treatments. Patients within
the standard care group were also asked whether they had a bra fitting, where this took
place, and if they took any other measures to relieve their breast pain. Demographic and
typical breast pain experience questions were removed from these surveys as these data
had already been collected.

Once patients had received their surveys (breast pain and SF-36) at four and eight weeks
they were given seven days to complete them. If no surveys were received contact was
made with the patient to prompt them. Contact was made on one final occasion after another
seven days if the surveys were still not received. Patients had the option to receive their
surveys either by post, or online via email, according to their preference which was
discussed with all patients when they consented to participate in the study. Patients who
decided to receive their surveys by post, had a stamped addressed envelope to return them.
This is a concurrent mixed-mode method of data collection (de Leeuw, 2005). Electronic
methods are typically preferred in ecological momentary assessment. Bowling (2005)
reported the risks of bias across thirteen factors and four modes of completion, including
postal and electronic self-completion methods. The postal and electronic methods were at
equal risk of bias across eight factors (two factors were not relevant for self-completion;
interviewer bias and length of verbal response). The three factors with potential for bias
were; respondent’s preference for mode (postal < electronic), question order effects (paper
> electronic, although the order of questions was kept consistent across modes to minimise
this) and a more complete population coverage for sampling (paper > electronic, however
this is irrelevant for this study as the survey was completed only by those who participated
in the study). The potential for bias is similar across both these methods although social
desirability could affect responses (Bowling, 2005). Social desirability bias could have
occurred if the patient felt there was a desirable response, for example, in this thesis,
patients were aware the bras were aiming to reduce their breast pain and improve their
QoL. Therefore, patients may have responded in a way to reflect this. However, this was
reduced as the surveys were not completed face-to-face or over the phone, where social
desirability is more common (Bowling, 2005).

6.3.6 Data Analysis; intervention outcome measures

6.3.6.1 Baseline Data

Means (±SD), modes, percentages and frequencies were calculated where appropriate for
demographic data. Chi squared and Mann-Whitney U tests were completed to assess for
any significant differences (p = 0.05) at baseline between the standard care and bra
prescription groups. Cramer’s V was calculated within SPSS as an effect size
measurement. Cramer’s V provides a score between 0 and 1 which shows the strength of association between the categorical variables, where a score of 0 equals no association. No effect sizes were calculated for the Freidman’s ANOVA test as these only show a general effect (Field, 2009). Effect sizes were only calculated in instances of the post hoc Mann-Whitney U pairwise comparisons being conducted. These effect sizes were calculated using the following equation (Field, 2009); \( r = Z/\sqrt{N} \). A medium effect is represented by an effect size of 0.3 and a large effect is represented by an effect size of 0.5 or greater (Field, 2009).

### 6.3.6.2 Primary Aim

To assess the primary aim (PGIC); a positive outcome is that a greater proportion of patients within the prescription group state that their general status is “much improved” or “very much improved” compared to the standard care group. A Fisher’s Exact Test was completed to assess the association between the groups (prescription or standard care) and whether patients felt their breast pain had; “very much improved” or “much improved”. Previous studies (Farrar et al., 2001) have determined that if a participant within the prescription group indicates that their general status is “much improved” (or better) this is a clinically significant result. This clinically significant result has been found to be comparable to a clinically significant reduction of minus 2 points on a NRS (Farrar et al., 2001).

### 6.3.6.3 Secondary Outcomes – breast pain intensity

Descriptive statistics on the NRS data showed the data (collected at baseline, four and eight weeks) were normally distributed and met assumptions for homogeneity of variance. Despite this, as this is ordinal data, non-parametric statistical tests were completed. A Friedman’s ANOVA was conducted to assess within-group comparisons (with the bra prescription group and the standard care group separately) and a Mann-Whitney U test was conducted to assess between group comparisons (between the bra prescription and standard care groups) at baseline, four and eight weeks. The alpha value for tests was set at 0.05.

### 6.3.6.4 Secondary Outcomes – QoL

Data from the SF-36 survey (collected at baseline, four and eight weeks) were scored according to the standard scoring algorithm. To calculate the PCS and MCS summary scores the method described in Ware, Jr. and Kosinski’s (2001) book was used (Figure 6.2).
Step 1: Calculations of scores based on standard SF-36 scoring algorithm see http://www.rand.org/health/surveys_tools/mos/36-item-short-form/scoring.html

Step 2: Z-score standardisation

<table>
<thead>
<tr>
<th>SF-36 Scale</th>
<th>Formula to convert to Z-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>$PF_Z = (PF-82.96845)/23.3879$</td>
</tr>
<tr>
<td>Role Limitations due to Physical Health</td>
<td>$RP_Z = (RP-77.93107)/35.385$</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>$BP_Z = (BP-70.22865)/23.3510$</td>
</tr>
<tr>
<td>General Health</td>
<td>$GH_Z = (GH-70.1060)/21.3500$</td>
</tr>
<tr>
<td>Energy/Fatigue (previously referred to as Vitality)</td>
<td>$VT_Z = (VT-66.99917)/21.12677$</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>$SF_Z = (SF-83.6594)/23.0276$</td>
</tr>
<tr>
<td>Role Limitations due to Emotional Health</td>
<td>$RE_Z = (RE-83.10276)/31.641.49$</td>
</tr>
<tr>
<td>Emotional Well-being (previously referred to as Mental Health)</td>
<td>$MH_Z = (MH-75.21913)/17.60698$</td>
</tr>
</tbody>
</table>

Step 3: Aggregation of Scales to Physical and Mental component scores

$$AGG\_PHYS = (PF\_Z^{0.42402}) + (RP\_Z^{0.35119}) + (BP\_Z^{0.31754}) + (GH\_Z^{0.24954}) + (VT\_Z^{0.02877}) + (SF\_Z^{0.00753}) + (RE\_Z^{0.19206}) + (MH\_Z^{0.22069})$$

$$AGG\_MENT = (PF\_Z^{0.22999}) + (RP\_Z^{0.12329}) + (BP\_Z^{0.09731}) + (GH\_Z^{0.1571}) + (VT\_Z^{0.23534}) + (SF\_Z^{0.26876}) + (RE\_Z^{0.43407}) + (MH\_Z^{0.48581})$$

Step 4: Transformation of Summary Scores

Transformed Physical (PCS) = 50 + (AGG\_PHYS * 10)
Transformed Mental (MCS) = 50 + (AGG\_MENT * 10)

Figure 6.2: Method of calculating the Physical Component Summary and Mental Component Summary from the SF-36 (Ware, Jr. & Kosinski, 2001).

Physical Component Summary and MCS scores at baseline, four and eight weeks were then assessed for normality. Data were not normally distributed, therefore non-parametric statistical tests were completed. For the between groups analysis Mann Whitney-U tests were conducted ($P = 0.05$). To assess the within-groups data (within the bra prescription group and within the standard care group), Friedman’s ANOVA’s ($P = 0.05$) were conducted followed by post hoc Wilcoxon’s signed rank tests with a Bonferroni Correction ($P = 0.016$).

6.3.7 Data analysis; bra prescription

The methods described in section 6.3.7.1 and 6.3.7.2 are summarised here, but fully detailed within Chapter Four of this thesis.
6.3.7.1 Comfort, Subjective Support, Subjective Fit and Aesthetics
These key performance indicators were measured using multiple VAS on an iPad (iPad Air 2). The patient marked a point along the VAS, and the app generated a number between 0 and 100.

6.3.7.2 Objective Support
Following the walking and stair activities markers were identified in Qualisys Track Manager Software (QTM, Qualisys, Sweden) and all data were exported as a C3D file. The C3D files were then used within Visual 3D software for analysis (C-motion, Version 5, USA). The static file was linked to each of the dynamic trials and a model was then created (section 4.1.2.5). For the walking trial and step activity, event markers identified five complete gait cycles or each step (section 4.1.2.5) and data were then analysed using Visual 3D, producing values for breast range of motion (mm), breast velocity (mm/s) and breast acceleration (mm/s²).

6.3.7.3 Breast Position
Breast position was assessed for descriptive purposes and did not influence the bra that was prescribed to the participant. Breast position relates to aesthetics as certain distances between the sternal notch and the nipple have been presented as more aesthetically pleasing (8 to 8.5 inches, approx. 21 cm; Penn (1955)). Although aesthetics may be associated with breast position, it is the patient who determines whether they find the bra aesthetically pleasing. This is why patients were asked to rate the bra for the shape it provides their breasts and also whether the bra makes them feel good.
Breast position was assessed using the static capture in QTM of the patients in each of the bras. Patients own everyday bra was used as a baseline position. Data from the static capture was exported into Visual 3D where a pipeline was created to assess the distance of the left and right nipple; anterioposteriorly, mediolaterally and superioinferiorly compared to the origin point. Left and right nipple positions were calculated individually and were not averaged. A comparison of distances (mm) between the STN and nipple markers were then compared to the patient’s own everyday bra to assess whether the position of the breasts was altered within the test bras.

6.4 Results

6.4.1 Participant Flow
Recruitment for this study commenced on the 13th October 2015 and was initially due to finish on the 25th February 2016. This recruitment period was extended due to low participant numbers to 14th April 2016. Recruitment ceased on this date despite patients’ numbers being much lower than anticipated.
Over the 25 weeks that recruitment was open a total of 3251 new patients were seen at the New Patient Breast Clinic. These patients were not solely those experiencing breast pain but many types of breast condition; this number also includes male patients with breast conditions. Of the 3251 patients, 64 were presented to the researcher for a full eligibility assessment and for full explanation of the study (Figure 6.3). This was after a pre-screen for eligibility was completed by the clinicians. Eligibility rate was 70%, consent rate was 73% and drop-out rates for the study were; 35% for the bra prescription group and 50% for the standard care group.

**Figure 6.3:** Patient flow chart showing the numbers of patients recruited into and who completed the bra intervention

### 6.4.2 Baseline Data

#### 6.4.2.1 Demographics

In the bra prescription group, bra size ranged from a 34 to 40 UK under band size and a C to F UK cup size. Patients that fell below the DD eligibility criteria (n = 3) were assessed by
the researcher and clinicians and were deemed eligible to participate as their current bra cup size was too small. Patients agreed with this evaluation and therefore were able to participate.

Within the standard care group, self-reported bra size ranged from 34 to 40 UK under band size and a D to F cup. Patients who reported wearing a D cup were in agreement with the researcher and clinicians who checked their bra fit during consultation, that they were wearing a bra that was too small. This meant they met the criteria of a minimum of a DD cup. Table 6.1 shows further demographic information about the patients within both groups.
Table 6.1: Demographics for the bra prescription group and standard care group

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Bra Prescription Group</th>
<th>Standard Care Group</th>
<th>Test Statistic</th>
<th>P</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>45 years (SD = 9)</td>
<td>32 years (SD = 6)</td>
<td>U = 9.00</td>
<td>0.004*</td>
<td>r = -0.65</td>
</tr>
<tr>
<td>Pre-menopausal</td>
<td>8</td>
<td>Pre-menopausal = 6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peri-menopausal</td>
<td>0</td>
<td>Peri-menopausal = 1</td>
<td></td>
<td>0.77</td>
<td>Cramers V = 0.28</td>
</tr>
<tr>
<td>Post-menopausal</td>
<td>2</td>
<td>Post-menopausal = 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Given birth?</td>
<td>Yes = 7</td>
<td>Yes = 6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No = 3</td>
<td></td>
<td>No = 2</td>
<td></td>
<td>1.000</td>
<td>Cramers V = 0.55</td>
</tr>
<tr>
<td>Number of children</td>
<td>2 (mode)</td>
<td>2 (mode)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were the children breastfed?</td>
<td>Yes = 8*</td>
<td>Yes = 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No = 2</td>
<td></td>
<td>No = 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the participant have</td>
<td>Yes = 4</td>
<td>Yes = 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>breast pain before children?</td>
<td>No = 4</td>
<td>No = 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contraceptive medication used</td>
<td>Yes = 1</td>
<td>Yes = 3</td>
<td></td>
<td>0.28</td>
<td>Cramers V = 0.33</td>
</tr>
<tr>
<td>No = 9</td>
<td></td>
<td>No = 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Types of contraceptive used</td>
<td>Oral contraceptive = 1</td>
<td>Oral contraceptive = 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English/Welsh/Scottish/Northern</td>
<td></td>
<td>English/Welsh/Scottish/Northern</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Irish/British = 10</td>
<td>Irish/British = 7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed/Multiple Ethnic Groups:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
* denotes a significant difference
* one participant had induced lactation following surrogate birth
6.4.2.2 Breast Pain

No significant differences in breast pain intensity (NRS) were found between the groups at baseline, however laterality of pain did significantly differ with the bra prescription most commonly experiencing breast pain in both groups, and the standard care group most commonly experienced breast pain in their right breast ($P = 0.008$) (Table 6.2).

Table 6.2: Breast pain factors at baseline for the bra prescription and standard care groups

<table>
<thead>
<tr>
<th>Breast Pain Factor</th>
<th>Bra Prescription Group</th>
<th>Standard Care Group</th>
<th>Test statistic</th>
<th>$P$</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast pain intensity (NRS)</td>
<td>6 (mode)</td>
<td>6 (mode)</td>
<td>$t(16) = 0.544$</td>
<td>0.594</td>
<td>$r = 0.13$</td>
</tr>
<tr>
<td>Pain pattern</td>
<td>Rhythmic/Periodic Brief/Momentary /Intermittent = 3 /Transient = 4 (mode)</td>
<td>Rhythmic/Periodic Brief/Momentary /Intermittent = 3 /Transient = 4 (mode)</td>
<td>0.139</td>
<td>Cramer’s V = 0.530</td>
<td></td>
</tr>
<tr>
<td>PPI</td>
<td>Discomforting = 7 (mode)</td>
<td>Discomforting = 4 (mode)</td>
<td>0.602</td>
<td>Cramer’s V = 0.405</td>
<td></td>
</tr>
<tr>
<td>Number of days of pain</td>
<td>17 days (SD = 8)</td>
<td>11 days (SD = 10)</td>
<td>$t(11) = 1.197$</td>
<td>0.256</td>
<td>$r = 0.35$</td>
</tr>
<tr>
<td>Number of years of pain</td>
<td>1 to 2 years (mode)</td>
<td>Less than 1 year (mode)</td>
<td>0.086</td>
<td>Cramer’s V = 0.060</td>
<td></td>
</tr>
<tr>
<td>Laterality of pain</td>
<td>Both breasts (mode)</td>
<td>Right breast (mode)</td>
<td>0.008*</td>
<td>Cramer’s V = 0.747</td>
<td></td>
</tr>
</tbody>
</table>

* denotes significant difference

For both groups, the outer half of the breast was the most painful area (Figure 6.4).

Figure 6.4: Location of breast pain (% distribution) across patients within the bra prescription group and the standard care group. (Participants could mark more than one area of the breast)
6.4.2.3 Quality of Life

There was no significant difference at baseline (Figure 6.5) between the two groups for the PCS ($t(16) = -1.798, P = 0.091$) or the MCS ($t(16) = 0.188, P = 0.853$).

![Figure 6.5: Baseline Quality of Life data (± standard deviation) for both groups presented as PCS and MCS summary scores.](image)

6.4.3 Outcomes and Estimation

6.4.3.1 Patient’s Global Impression of Change

At four weeks in the bra prescription group, 55% (5/9 patients, 1 patient’s data was missing at four weeks) reported their breast pain to be ‘much improved’ or ‘very much improved’ (clinically significant improvement), compared to 45% (4/9 patients) who reported their breast pain to be ‘minimally improved’ (n = 3) or they felt they had ‘no change’ in breast pain (n = 1). Twenty-five percent (2/8 patients) of patients in the standard care group at four weeks felt their pain had ‘much improved’ or ‘very much improved’ (clinically significant improvement) compared to 75% (6/8) who felt their breast pain at four weeks had ‘minimally improved’ (n = 2), had ‘no change’ (n = 3) or become ‘minimally worse’ (n = 1). Despite the differences in the proportions of patients who had a clinically important improvement in their PGIC rating in the bra prescription group, at four weeks there were no significant differences between the groups ($P = 0.335$, Fisher’s Exact Calculation, Cramer’s $V = 0.310$), although the study had low statistical power (post hoc power = $\beta = 0.56$, calculated for post hoc power in G*Power using the same methods as Chapter five, section 5.5).

At eight weeks, 50% of patients (5/10) within the bra prescription group reported a clinically significant improvement in their breast pain (‘much improved’ or ‘very much improved’). The remaining 50% of patients reported a ‘minimally improved’ (n = 2) status or ‘no change’ (n = 3). For the standard care group, 25% of patients (2/8) reported their breast pain had ‘much
improved’ or ‘very much improved’ compared to 75% (6/8) who reported their breast pain ‘minimally improved’ (n = 4) or they reported ‘no change’ (n = 2). There was also no statistically significant difference between the groups at eight weeks ($P = 0.367$, Fisher’s Exact Calculation, Cramer’s $V = 0.255$).

### 6.4.3.2 Breast Pain

More patients within the standard care group saw a bigger drop in pain compared to the bra prescription group (Table 6.3).

**Table 6.3:** Change in Numerical Rating Scale score (from baseline) for each patient within the bra prescription and standard care group. Baseline NRS scores are presented with a positive improvement or negative change in score reported for four and eight weeks following the bra prescription or standard care.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Baseline</th>
<th>Four</th>
<th>Eight</th>
<th>Patient</th>
<th>Baseline</th>
<th>Four</th>
<th>Eight</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP1</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>SC1</td>
<td>3</td>
<td>0*</td>
<td>0*</td>
</tr>
<tr>
<td>BP2</td>
<td>7</td>
<td>4*</td>
<td>0*</td>
<td>SC2</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>BP3</td>
<td>3</td>
<td>5</td>
<td>6</td>
<td>SC3</td>
<td>6</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>BP4</td>
<td>5</td>
<td>1*</td>
<td>4</td>
<td>SC4</td>
<td>7</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>BP5</td>
<td>6</td>
<td>-</td>
<td>7</td>
<td>SC5</td>
<td>6</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>BP6</td>
<td>4</td>
<td>6</td>
<td>3</td>
<td>SC6</td>
<td>5</td>
<td>2*</td>
<td>2*</td>
</tr>
<tr>
<td>BP7</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>SC7</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>BP8</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>SC8</td>
<td>6</td>
<td>5</td>
<td>3*</td>
</tr>
<tr>
<td>BP9</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP10</td>
<td>3</td>
<td>3</td>
<td>1*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Mode    | 6        | Multimodal: 3/5/6 | Bi-modal: 3/6 | 6 | No mode | Bi-modal: 2/7 |

* denotes clinically significant change
- missing data

There was no significant difference within the groups across the measurements at baseline, four and eight weeks (bra prescription group; $\chi^2 = 1.040$, $P = 0.640$; standard care groups; $\chi^2 = 4.455$, $P = 0.169$). There was also no significant difference between the groups at each time point (baseline; $U = 36.500$, $P = 0.780$, $r = 0.75$, four weeks; $U = 31.500$, $P = 0.691$, $r = 0.11$, eight weeks; $U = 31.500$, $P = 0.472$, $r = 0.18$).

### 6.4.3.3 QoL

On average a greater improvement in QoL was seen for the PCS scores (+5.2 at four and eight weeks) and MCS scores (+3.8 at four weeks and +3.7 at eight weeks) for the bra
prescription group compared to the standard care group compared to baseline (Table 6.4). These improvements were not however statistically significant ($P > 0.05$).

**Table 6.4:** Baseline PCS and MCS scores for both groups with changes from baseline at four and eight weeks post intervention/receipt of standard care.

<table>
<thead>
<tr>
<th>Bra Prescription Group - PCS</th>
<th>Standard Care Group - PCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Baseline</td>
</tr>
<tr>
<td>BP1</td>
<td>52.4</td>
</tr>
<tr>
<td>BP2</td>
<td>58.7</td>
</tr>
<tr>
<td>BP3</td>
<td>36.4</td>
</tr>
<tr>
<td>BP4</td>
<td>53.2</td>
</tr>
<tr>
<td>BP5</td>
<td>53.3</td>
</tr>
<tr>
<td>BP6</td>
<td>46.5</td>
</tr>
<tr>
<td>BP7</td>
<td>37.2</td>
</tr>
<tr>
<td>BP8</td>
<td>53.4</td>
</tr>
<tr>
<td>BP9</td>
<td>53.7</td>
</tr>
<tr>
<td>BP10</td>
<td>48.0</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>49.3</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bra Prescription Group - MCS</th>
<th>Standard Care Group - MCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Baseline</td>
</tr>
<tr>
<td>BP1</td>
<td>57.2</td>
</tr>
<tr>
<td>BP2</td>
<td>43.2</td>
</tr>
<tr>
<td>BP3</td>
<td>50.3</td>
</tr>
<tr>
<td>BP4</td>
<td>36.5</td>
</tr>
<tr>
<td>BP5</td>
<td>51.1</td>
</tr>
<tr>
<td>BP6</td>
<td>29.6</td>
</tr>
<tr>
<td>BP7</td>
<td>34.1</td>
</tr>
<tr>
<td>BP8</td>
<td>57.8</td>
</tr>
<tr>
<td>BP9</td>
<td>50.1</td>
</tr>
<tr>
<td>BP10</td>
<td>46.2</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>45.6</strong></td>
</tr>
</tbody>
</table>

* denotes clinically significant change  
- missing data

### 6.4.3.3.1 Between groups

For the PCS score, at both four and eight weeks there were no significant differences between the groups (four; $U = 16.000$, $P = 0.059$, $r = -0.46$; eight; $U = 35.000$, $P = 0.696$, $r = -0.10$), this was the same for the MCS score (four; $U = 30.000$, $P = 0.606$, $r = -0.14$; eight; $U = 26.000$, $P = 0.237$, $r = -0.29$).
6.4.3.3.2 Within Groups

The Friedman's ANOVA showed a significant improvement in the PCS score for the bra prescription group ($\chi^2 = 8.667, P = 0.010$), but no significant difference in the standard care group ($\chi^2 = 2.250, P = 0.355$) across the eight week intervention period. Wilcoxon post hoc tests ($P = 0.016$) for the bra prescription group showed a significant improvement between baseline and eight weeks ($Z = 2.701, P = 0.004, r = 0.60$), but no significant difference between baseline and four weeks ($Z = -2.310, P = 0.02, r = -0.53$) or between four and eight weeks ($Z = -0.059, P = 1.000, r = -0.01$) (Figure 6.6).

![Figure 6.6](image_url)

**Figure 6.6**: Within patients change in PCS score over time. * denotes a statistically significant result.

There was no significant difference within either group for the MCS summary scores (bra prescription group; $\chi^2 = 0.667, P = 0.814$; standard care; $\chi^2 = 1.750, P = 0.531$) (Figure 6.7).

![Figure 6.7](image_url)

**Figure 6.7**: Within patients change in MCS score over time.
6.4.3.3 *Individual component improvements for the bra prescription group (PCS)*

As there was a statistically significant improvement within the bra prescription group for the PCS summary scores further investigation was completed to assess where these statistically significant improvements occurred within the SF-36 individual components. The emotional well-being and pain components had an increase at four weeks which continued to improve at eight weeks (Figure 6.8). Additionally, a clinically significant improvement occurred across the mean scores for each component of the PCS summary scores, except for between baseline and four weeks for the general health domain.

![Graph showing changes in component score from the SF-36 for the bra prescription group at baseline, four and eight weeks. A higher score demonstrates an improvement in QoL (* denotes statistically significant result).](image)

**Figure 6.8:** Changes in component score from the SF-36 for the bra prescription group at baseline, four and eight weeks. A higher score demonstrates an improvement in QoL (* denotes statistically significant result).

6.4.4 Additional Analyses

6.4.4.1 Standard Care Group; adherence to standard care

At four weeks, 38% (3/8) of the standard care group had received a bra fitting (Marks and Spencer; n = 2 and Bravissimo; n = 1), by eight weeks two additional patients had received bra fittings (Marks and Spencer; n = 1 and Ann Summers; n = 1). Out of the five patients who received a bra fitting, only one changed bra sizes from a 32E to 34D. This patient reported that she brought new bras but continued to wear her old bras as well. The reasons given for the patients who did not get a bra fitting (at four weeks) were; a lack of time (n = 2), not being able to afford new bras (n = 2) and not knowing where to be fitted (n = 1). The
reasons given by the three remaining patients at eight weeks were; a lack of time (n = 1), not being able to afford new bras (n = 1) and that the patient wore sports bras therefore a bra fitting was not needed (n = 1).

Topical ibuprofen gel was used by two patients at four weeks and an additional three patients at eight weeks. At four weeks the patients reasons for not using the topical ibuprofen were that; they were not recommended or advised to use it, despite this being the standard care (n = 4), they felt their pain was not sufficient enough (n = 1), and they forgot to purchase and use the topical ibuprofen (n = 1) (when asked at eight weeks the participant reported she was now using the topical ibuprofen). The Breast Cancer Care leaflet on breast pain was used for advice by 100% of patients at four weeks and 88% (n = 7) at eight weeks. Lifestyle changes were also reported by patients in the standard care group, a change in diet was reported by two patients at four weeks (healthier diet; n = 1, poorer diet; n = 1), four patients at eight weeks (healthier diet; n = 3, poorer diet; n = 1). At four weeks, three patients reported to have changed their level of exercise with two patients increasing the volume of light activities they undertook and another attending a spinning class once per week. Only two patients reported changing exercise habits at eight weeks; one increasing the amount of walking (reported at four weeks also) and the other had started jogging. At four weeks, three patients reported the use of additional medications since the start of the study; evening primrose oil and vitamin B6 (n = 1), ibuprofen and paracetamol (n = 1), and ibuprofen on its own (n = 1). Throughout the study, no patients reported changing any contraceptive medications.

6.4.4.2 Bra Prescription Group; adherence to prescribed bra and standard care

Patients in this group reported how often they wore the prescribed bra; five (50%) reported wearing the bra every day, one (10%) reported wearing the bra a couple of days per week and another patient (10%) reported wearing the bra most days but not when she wore evening outfits. Two patients (20%) did not answer this question and one patient (10%) did not complete the four week survey. By eight weeks, six patients reported wearing the bra every day, and three reported wearing the bra a couple of times per week and one patient (10%) did not answer this question. Over the eight weeks three patients (30%) purchased additional bras in the size they were fitted in at the University of Portsmouth, from Next (n = 1), Debenhams (n = 1) and Shock Absorber (n = 1). One of these patients also continued to wear her old bras.

No patients within the bra prescription group used the topical ibuprofen gel across all eight weeks. At four weeks the reasons given for not using the ibuprofen were; not being
recommended or advised to use, despite this being standard care (n = 4), they felt their pain was manageable or the ibuprofen was not needed (n = 2), that their pain was not constant (n = 1), they wanted to try the bras first (n = 1) and they were waiting for stronger medication from a gynaecology referral (n = 1). At eight weeks, seven patients (70%) reported not being advised or recommended to use the topical ibuprofen, two reported not needing it and one continued to report that they wanted to try the bra first. At four weeks three patients (30%) reported that they used the Breast Cancer Care leaflet on breast pain and at eight weeks three patients (30%) reported using the leaflet (only one patient was the same from the four week survey responses). This meant five (50%) patients in total reported using the Breast Cancer Care leaflet.

Patients reported the following lifestyle changes at four weeks; two patients reported changing their diet; one to take evening primrose oil (which was reported by a patient within the standard care group as a change in medication) and another reported starting Weight Watchers®. At eight weeks one additional participant reported she was drinking less red wine. At four weeks two patients reported changing their exercise levels, increasing their volume of exercise by running (n = 1) or walking (n = 1) this was reported by the same patients at eight weeks. An additional three patients also reported increasing their exercise levels at eight weeks; by walking (n = 1) and a general increase in exercise (n = 1, type of exercise not specified). At four weeks one patient reported stopping the contraceptive pill but no other patient reported stopping or starting any additional medications or contraceptives at four or eight weeks.

6.4.5 Bra prescription session; Results

Patients were given a bra that made an improvement to their own bra and scored highest overall across the four KPI’s (Table 6.5). Of the 11 participants, eight participants were prescribed a bra in a different size to the bra they arrived in and two were prescribed a bra in the same size as their own everyday bra. One participant was wearing a well-fitting bra on arrival and none of the testing bras performed better than her own everyday bra.
Table 6.5: Bra sizes of patients attending the laboratory, plus the size they were fitted in, in each of the testing bras.

<table>
<thead>
<tr>
<th>Patients own bra</th>
<th>Fitted Size - shaded size was the bra prescribed to the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Size</td>
</tr>
<tr>
<td>P1</td>
<td>34D(^+)</td>
</tr>
<tr>
<td>P2</td>
<td>34E</td>
</tr>
<tr>
<td>P3</td>
<td>36E</td>
</tr>
<tr>
<td>P4</td>
<td>34DD</td>
</tr>
<tr>
<td>P5</td>
<td>34D(^+)</td>
</tr>
<tr>
<td>P6</td>
<td>38C(^+)</td>
</tr>
<tr>
<td>P7</td>
<td>38E or F (cup size unreadable on label)</td>
</tr>
<tr>
<td>P8</td>
<td>40F</td>
</tr>
<tr>
<td>P9</td>
<td>42D(^+)</td>
</tr>
<tr>
<td>P10</td>
<td>38DD</td>
</tr>
<tr>
<td>P11</td>
<td>34E</td>
</tr>
</tbody>
</table>

\(^*\) patient reported to be a DD\(^+\) cup size at the point of recruitment but attending the clinic wearing a smaller bra cup size

\(^*\) ranking score is given based on the five point best fit criteria. A score of 5 = meets all criteria, 0 = meets none of the criteria

\(^*\) brand is unknown due to unreadable label. Patient was also unable to remember where the bra was purchased

\(^\text{excluded as good fit was unattainable}\)
A ranking of one demonstrates that the bra was ranked highest for each variable and then the lowest ranking number (which varies dependant on the number of bras tested) demonstrates the bra that performed worst for each variable (Figure 6.9). Patient 1 was the only person to be prescribed a bra which ranked highest for all four KPI’s; comfort, support, aesthetics and fit. Patient 11 was the only person to test all of the bras, and the bra they were prescribed ranked highest for comfort, aesthetics and fit, but ranked last for support.
Figure 6.9: Key Performance Indicator rankings for each bra and for each participant (P1 to P11). Prescribed bra is represented by the grey line.

6.4.5.2 Overall ranked position

The bras prescribed to patients varied not only in size but also in final rankings (Table 6.6). Bra 1 fitted five patients within the study and was prescribed to three of the patients it fitted, Bra 2 fitted 6 patients but was only prescribed to one participant, Bra 3 fitted only four patients within this study, but out of the patients it did fit, it was prescribed on two occasions. This was compared to Bra 4 which fitted the same amount of patients as Bra 3 but was not prescribed to any participant. Bra 5 fitted 8 patients and was prescribed on 3 occasions. Whereas Bra 6, which fitted the most patients overall (n = 9), was only prescribed on one occasion.
### Table 6.6: Overall rankings for each bra and for each participant. The bra that scored 1 for each participant was prescribed.

<table>
<thead>
<tr>
<th></th>
<th>Bra 1</th>
<th>Bra 2</th>
<th>Bra 3</th>
<th>Bra 4</th>
<th>Bra 5</th>
<th>Bra 6</th>
<th>Patients own bra*</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>-</td>
<td>3</td>
<td>1</td>
<td>-</td>
<td>4</td>
<td>2</td>
<td>No ranking</td>
</tr>
<tr>
<td>P2</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>3</td>
<td>1</td>
<td>-</td>
<td>No ranking</td>
</tr>
<tr>
<td>P3</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>4</td>
<td>3</td>
<td>No ranking</td>
</tr>
<tr>
<td>P4</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>No ranking</td>
</tr>
<tr>
<td>P5</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>No ranking</td>
</tr>
<tr>
<td>P6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>1</td>
<td>No ranking</td>
</tr>
<tr>
<td>P7</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>-</td>
<td>2</td>
<td>No ranking</td>
</tr>
<tr>
<td>P8</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>No ranking</td>
</tr>
<tr>
<td>P9</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>No ranking</td>
</tr>
<tr>
<td>P10</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>-</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>P11</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>6</td>
<td>2</td>
<td>4</td>
<td>No ranking</td>
</tr>
</tbody>
</table>

* patients own bra was only included in the ranking if it score 5 out of 5 on the best fit criteria
* excluded as a good fit was unattainable

#### 6.4.5.3 Breast position

On average (mean, across both breasts) in their prescribed bras, patient’s breasts (defined by the nipple) were further projected by 1 mm, separated by 4 mm and lifted by 19 mm compared to their own bra (Figure 6.10).
Randomised controlled trial; a bra intervention study
Randomised controlled trial; a bra intervention study
Randomised controlled trial; a bra intervention study
Figure 6.10: Breast position (mm) in the anteroposterior, mediolateral and superioinferior directions for each participant in each bra tested. The origin point of this measurement is the Suprasternal Notch marker.

6.4.5.4 Comparison of prescribed bra to intervention data
The results of the bra prescription and the outcome measures (PGIC, NRS and QoL) are summarised below (Table 6.7).
Table 6.7: Prescribed bra plus its ranking for each of the key performance indicators (comfort, support, fit and aesthetics), positional changes compared to the patients own bra and the effects of the prescribed bra on PGIC, Breast Pain and QoL.

<table>
<thead>
<tr>
<th>Participant Number and Prescribed Bra</th>
<th>KPI Ranking</th>
<th>Positional Change*</th>
<th>Effect on Breast Pain and QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A/P (RL)</td>
<td>M/L (RL)</td>
<td>S/I (RL)</td>
</tr>
<tr>
<td>P1 - Bra 2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P2 - Bra 5</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>P3 - Bra 1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P4 - Bra 3</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P5 - Bra 5</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P6 - Bra 6</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>P7 - Bra 1</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P8 - Bra 5</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>P9 - Bra 1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P10 - Excluded from the study as no improvement could be made on their own bra</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P11 - Bra 2</td>
<td>1</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

* For positional changes compared to the participants own bra changes are reported as right breast followed by left breast and as follows: values away from origin ↗ (A/P), ↗ (right breast; M/L), ↗ (left breast; M/L) and ↗ (S/I). Values closer to origin reported as ↗ (A/P), ↗ (right breast; M/L), ↗ (left breast; M/L) and ↗ (S/I). Two arrows are shown in each box to represent the positional effect on the left and right breast individually. The first arrow represents the right breast and the second arrow represents the left breast.

<sup>a</sup> PGIC resulted abbreviated to: VMI = Very Much Improved, Mi = Much Improved, Minl = Minimally Improved, NC = No Change, MinW = Minimally Worse, Mw = Much Worse and VMM = Very Much Worse

<sup>b</sup> Change from baseline

<sup>#</sup> Clinically significant improvement

- missing data
The bra prescribed to P1 was ranked 1st across all KPI's. The position of the patients breasts in this bra was more compressed, more centralised and one breast was lifted compared to their own everyday bra. Despite being ranked 1st across all KPI's there were no clinically significant changes in the PGIC or the NRS. There was a clinically significant improvement in PCS at four weeks but this did not continue at eight weeks and there was no significant improvement in the MCS.

Conversely, P2 had a bra prescribed which was not the most supportive or aesthetically pleasing but most comfortable and rated best for subjective fit. Their breasts were not compressed (compared to their own everyday bra) and they were separated and lifted. This participant saw a clinically significant improvement in their PGIC after eight weeks and they saw the greatest clinically significant reduction in breast pain across the eight weeks. They did not have a clinically significant improvement in the PCS components of QoL but did see clinically significant improvements in the MCS at four and eight weeks.

Interestingly, the final patient (P11) had a bra prescribed that was the least supportive out of the bras they tested. Despite this, all outcome measures saw clinically significant results (other than the NRS at four weeks). Similar to P2, this patients breasts were also projected and the breasts were lifted although the medial/lateral positioning was different.

### 6.5 Conclusions and Summary

The key findings of this study were;

- Recruitment and retention of patients was poor making it difficult to fully evaluate the effect of the bra prescription on breast pain and QoL
- Despite this, QoL significantly improved within the bra prescription group
- The adherence to wearing the bras was high, but low for the use of topic ibuprofen gel
- 91% of patients in the bra prescription group were wearing a poorly fitting bra
- The bras prescribed to each patient varied in the ranking they were provided across the four KPI's

The MRC 2008 guidelines (Craig, Dieppe, Macintyre, Michie, et al., 2008; Levati et al., 2016; Figure 6.11) outline the four stages of developing a complex intervention. Chapters Two to Five focused on the development phase. This chapter is the pilot study (second phase) and will be followed by the evaluation phase (third phase). The effectiveness of the intervention will be considered and the development and piloting phases will be reviewed. This chapter will conclude by determining whether the RCT can be implemented in its current form, or if more development work is required.
Figure 6.11: Medical Research Council 2008 guidelines for developing an complex intervention.
Chapter Seven: Evaluation Phase: Evaluating the effectiveness of the bra intervention.

7.1 Introduction

The process of developing an intervention does not have to take a linear approach; it can be cyclical, or the phases can be completed in a variety of orders (Craig, Dieppe, Macintyre, Mitchie, et al., 2008). Campbell et al. (2000) suggested that the process of developing an intervention should be iterative, whereby ineffective and effective areas are identified through evaluation and the ineffective parts should be improved upon.

7.2 Aim

The aim of this chapter is to identify where the bra intervention has been effective or ineffective.

7.3 Recruitment

The main limitation of the bra intervention was the sample size. A post hoc power tests was calculated on G*Power using the PGIC data at eight weeks and determined the study power to be $\beta = 0.56$, lower than the recommended $\beta = 0.80$ (Cohen, 1988). Studies which have low statistical power, such as this RCT, are unlikely to detect small changes which can including clinically or economically significant results (Sturm, Unutzer, & Katon, 1999). As statistical power increases, the likelihood of a type 2 error (false negatives) decreases (Biau, Kernels, & Porcher, 2008). A type 2 error is when no difference is reported, yet this difference does exist (Biau et al., 2008). As the RCT was underpowered, it is possible that there could be differences that have not yet been detected within the bra intervention, and so improving recruitment into the study would aid in identifying whether there were statistical differences in the PGIC, breast pain and QoL.

There are three main factors which could have influenced the level of recruitment and they will each be discussed in turn:

- Low volumes of patients attending the clinic with breast pain
- Restrictive eligibility criteria
- Lack of interest in the study (those who chose not to participate)

Firstly, it is possible that the volume of patients reporting with breast pain at the clinic is lower than expected based on existing literature. Only 2% of the total patients seen within the clinic were assessed for eligibility, this is despite literature suggesting that the majority of breast clinics see patients reporting with breast pain and 52% of the UK general population experience breast pain (Scurr et al., 2014; Tavaf-Motamen et al., 1998). Anecdotal evidence from the clinicians at the QA Hospital had suggested the numbers of
patients with breast pain in the clinic were high and recruitment would not be an issue for this study. There have been no studies within the UK addressing the prevalence of breast pain in UK clinics. This is therefore something that should be investigated further.

The clinicians at the QA Hospital were initially screening patients before bringing them to the researcher for a full eligibility assessment. This involved checking the patients self-reported bra size and ensuring they were reporting with breast pain. It is possible that not all clinicians were fully on board with the bra intervention. The researcher had a closer relationship with two clinicians who were involved in the set-up of the study, therefore the relationship with the other clinicians may not have been as strong. Over time this relationship may have improved aiding recruitment, which in turn could have led to a higher number of patients being brought to the attention of the researcher and increase the volume of patients who were assessed for eligibility. Sandberg et al. (2002) highlighted the importance of the clinician-researcher relationship. Developing the communication and levels of trust, but also by working with clinicians to propose how the research can be tailored to clinical practise would aid in improving this relationship (Sandberg et al., 2002).

This was completed to a degree with the clinicians at the QA Hospital, however, as this was the first collaborative project between the clinic and the Research Group in Breast Health, the relationship is still new and can be further developed. Time is a large barrier to clinicians being involved in clinical research (Sandberg et al., 2002).

The bra size criteria may have restricted the number of patients who were assessed for eligibility. Women with larger breasts were the focus for this study as they may be more likely to wear ill-fitting bras due to the size and shape of the breasts (Greenbaum et al., 2003) and the traditional method of bra fitting is less accurate as bra size increases (White & Scurr, 2012). It is suggested that breast size is also increasing, with increases in bust circumferences being presented for White British women (Brown & Scurr, 2016) although the evidence is limited. Other bra/breast pain studies have also used women with larger breasts within their studies (Hadi, 2000; Wilson & Sellwood, 1976). It is currently unknown what proportion of patients have larger bra sizes compared to smaller bra sizes within a clinic population. This also could be investigated and could show whether the inclusion criteria may have been a limiting factor. This bra size restriction was also in place for financial reasons, see the cost benefit analysis in section 7.9.

A final consideration for recruitment is the interest in the study. Twelve patients out of 64 (19%) who were assessed for eligibility were not interested in taking part in the study (Figure 6.3). This is a significant problem as potential participants were lost due to a lack of interest in participating. When participants were assessed for eligibility they were also given the full information about the study. Brewin and Bradley (1989) report that it is vital participants
within randomised controlled trials are aware of the full information, including the random allocation, problems or side effects, and any commitment they need to make which might disrupt their normal routine. Conversely, patients may also have been put off participating in the study once they were aware of the full details as they may have not wanted to be assigned to a particular group. Additionally, the patients who chose not to participate in the study may have had other barriers to participating. An investigation of the level of interest within a clinic population may be key to understanding why recruitment was poor within this study. A further study should also investigate the barriers to taking part in the bra intervention study, so it can be improved and become more accessible. This may identify operational problems which could be amended to ensure the intervention fits the needs of the study population.

7.4 Retention

The dropout rate was high indicating that there was some detachment from the patients who had consented. Schulz and Grimes (2002) reported drop-out rates greater than 20% have potentially serious threats to validity, and less than 5% drop-out would have little bias. In the bra prescription group 41% of recruited participants dropped out, with 86% dropping out prior to attending the bra prescription session. In the standard care group, 50% dropped out over the monitoring period.

The RCT is classed as the gold standard for intervention based studies to determine the effectiveness of the trial (Campbell et al., 2000). This is because the randomisation of participants is designed to ensure there is equal distribution in things like age (across the two groups) (Brewin & Bradley, 1989). Patient preferences and motivation, however, may affect the results obtained and without considering these, patients may drop out (Brewin & Bradley, 1989). Brewin and Bradley (1989) report that this is particularly a problem in participatory studies such as the bra intervention study, as participants need to have motivation to be involved.

Patients may volunteer to be a part of an RCT because they have a preference for a particular treatment and want to be allocated to their preferred group (Brewin & Bradley, 1989; Torgerson & Sibbald, 1998). Then, when they are allocated to their non-preferred group, they drop out because their motivation is then reduced (Brewin & Bradley, 1989) or, they may continue in the study and not comply, introducing bias to the study (Torgerson & Sibbald, 1998). This may explain why 50% of participants within the standard care dropped out. It does not however explain why 41% of participants in the bra prescription group dropped out.
Evaluating the bra intervention

Brewin and Bradley (1989) also suggest that participants may drop out of a study if they feel they are not suitable for the treatment. Due to the nature of the study, participants were required to give informed consent at the hospital following their appointment with the clinicians, this process was completed to randomise the participants and to minimise the amount of visits they were required to make. This, however, may have put pressure on patients to agree to participate. After further consideration of the study outside of the hospital environment the patients may have felt they were unsuitable or that they did not want to participate. It is therefore important that the barriers to participating in the bra intervention are investigated.

A patient preference trial may also be useful to run alongside an RCT and could have aided recruitment in this study. The study could not be blinded, and the two treatment arms (bra prescription and standard care) are very different. A patient preference trial is where four groups are involved; 1. Those who have a preference for the intervention (bra prescription) group, 2. Those who have a preference for the control (standard care) group, 3. Those with no preference who get randomly allocated to the intervention (bra prescription) group and 4. Those with no preference who get randomly allocated to the control (standard care) group (Torgerson & Sibbald, 1998). This allows for a partially randomised trial to be conducted. Although the outcome of the preference groups cannot be compared to the randomised groups, the preference groups could be treated as observational studies adding to the results (Torgerson & Sibbald, 1998). Torgerson and Sibbald (1998) recommend that a preference trial should be conducted to complement an RCT not to replace it. This type of trial could be considered if the bra intervention were to be run again.

### 7.5 Outcome

#### 7.5.1 PGIC

The primary aim was to investigate whether a prescribed bra resulted in a higher number of patients within the bra prescription group rating their breast pain as “very much improved” or “much improved” on the PGIC scale compared to the standard care group. This was followed by secondary aims to; assess whether breast pain intensity and QoL improved at four and/or eight weeks following a bra prescription compared to the effect of standard care alone, to assess whether breast pain intensity and QoL improved at four and/or eight weeks following a bra prescription within the prescription group, and patient’s adherence to the study treatments.

No significant difference was reported between the groups at four or eight weeks for the PGIC, despite a higher proportion of patients (55% at four weeks and 50% at eight weeks) in the bra prescription group reporting their breast pain to be “very much improved” or “much
improved. These PGIC values are lower than the reported percentage (85%) of patients who obtained relief from breast pain by using a sports bra (Hadi, 2000), and the 75% of patients reporting a positive outcome from breast pain (complete relief/improved status) in the study by Wilson and Sellwood (1976). A higher number of patients within the bra prescription group did, however, achieve a clinically significant improvement (Younger et al., 2009) compared to the standard care group (55% at four weeks and 50% eight weeks for the bra prescription group compared to 25% at four weeks and 25% at eight weeks for the standard care group). Despite the non-significant statistical results, it is important that no patient within the bra prescription group reported their condition worsened over the eight weeks. At four weeks, one patient within the standard care group reported that their condition was minimally worse. The lack of statistical findings may be due to the low sample size and not achieving the recommended statistical power.

### 7.5.2 Breast Pain

There was no statistically significant difference in breast pain intensity between the bra prescription group and standard care group at four or eight weeks. It is possible that the monitoring period was not long enough to see a significant result, perhaps lengthening this would show some significant improvements within the bra prescription group. Two patients also saw an increase in breast pain over the monitoring period which may have been due to confounding variables.

Previous studies have also indicated that a clinically significant reduction in NRS score is a reduction of 2 points on the scale (Younger et al., 2009). Averaging scores for both groups did not show a clinically significant improvement, 22% of patients at four and 20% of patients at eight weeks achieved this clinically significant improvement in the bra prescription group. In the standard care group, 25% of patients at four weeks and 38% at eight weeks also achieved this clinical significance. Three out of 10 patients were experiencing breast pain lower than the clinically important intensity (4 out of 10) (Ader & Browne, 1997), therefore it is possible that the bra prescription is less effective for women with low intensity breast pain, although a clinically significant result was seen with one.

There was no significant difference within the bra prescription group between the measurements at baseline, four and eight weeks, and rejecting hypothesis 3. No significant differences were also seen within the standard care group, accepting hypothesis 4. It is important that there was no significant difference between the groups at baseline as this shows the two groups were similar prior to the bra prescription and standard care being provided. Additional research may also consider assessing whether patients in both groups were experiencing fibromyalgia or vitamin D deficiency, as both have been suggested to
have a link to breast pain (Alipour et al., 2015; M. Sen et al., 2015; Smith et al., 2004), therefore if patients had these underlying conditions, this may have affected the results seen in this study.

### 7.5.3 QoL

Quality of life is affected by breast pain (Bahadir.Ozturk et al., 2015; Carmichael et al., 2006; Colegrave et al., 2001). Hadi (2000) reported that the sports bra improved QoL of users, but it is unclear how QoL was measured and what aspects of QoL were improved. There was also no statistical analysis to show whether there was a significant improvement in QoL following the use of a sports bra compared to the pharmacological treatment received by the other participant group. This suggests that the current study may be the only study to fully assess QoL, both physically and mentally, following the introduction of a bra with the aim to reduce breast pain.

#### 7.5.3.1 Between groups

There were no significant differences in the PCS and MCS summary scores at baseline, indicating similarities in the groups at the start of the study. However, no statistically significant differences were seen between the groups at each time point for either the PCS or MCS. However, more clinically significant improvements were reported for the bra prescription group for both the PCS and MCS with 67% of the bra prescription group reporting an improvement at four weeks and 70% at eight weeks in the PCS, and 55% saw a clinically significant improvement at four weeks MCS and 50% at eight weeks in the MCS. Other than Hadi (2000) who suggested improvements in QoL, other research in the area of bras as a treatment for breast pain (Wilson & Sellwood, 1976; Woollett et al., 2012) have not investigated the effects on QoL, so the current study presents a new finding, demonstrating the benefit on physical QoL of wearing an appropriate bra for women with larger breasts and breast pain.

#### 7.5.3.2 Within groups

There was no significant improvement in the MCS compared to baseline within the bra prescription group despite a positive trend in the data (Figure 6.7). There was a significant improvement for the PCS between baseline and eight weeks for the bra prescription group. The strong effect size in the comparison between baseline and four weeks ($r = -0.53$) for the PCS suggests an increase in the sample size may have resulted in a significant value. Considering the data further there was a statistically significant improvement in the physical functioning component, the energy/fatigue component and the pain component at four weeks compared to baseline. The improvement in the pain component demonstrates a positive benefit of the bra prescription and suggests some improvement in pain irrespective
of the results of the NRS. All components of the SF-36 (in the bra prescription group) had a clinically significant improvement (≤5 point improvement) except for the general health component (which improved but not significantly) between baseline and four weeks. It has been suggested that improving bras for breast cancer survivors could potentially influence QoL (Gho et al., 2014), and this thesis confirms this for breast pain sufferers. It is important to understand the effect that bras can have on QoL as it can affect both physical and mental QoL. No statistically significant improvements in the PCS or MCS were found in the standard care group.

A consideration is whether the patients were monitored for long enough for an effect to be seen. It is difficult to confirm whether the intervention was long enough, as no previous study has identified how long a bra should be worn to reduce side effects. It would have been prudent to have a longer intervention period to identify whether breast pain was reduced or QoL improved over a longer period. This was unfeasible with patients from the clinic as determined in section 5.3 due to the timings of other treatment. Or, it may be that the bra prescription is not as effective as hoped, or, as reported in Brewin and Bradley (1989) and Campbell et al. (2007) it could be that the bra prescription is appearing less effective as it has been; targeted at the wrong cohort, targeted at a group with low motivation, or the intervention may have been inadequately applied or applied in the wrong context.

7.6 Adherence

It is important to assess how participants within the intervention adhered to the treatments, as high adherence cannot be assumed (Vermeire & Hearnshaw, 2001). It is vital to assess adherence for the prescribed bra and the standard care that both groups were instructed to follow. It is also important for the clinicians within the QA Hospital to understand how their standard care is applied within the clinic. Adherence was measured indirectly within this study, which could have led to over-estimations (Vermeire & Hearnshaw, 2001) as participants may report higher adherence than what actually happened. To improve adherence participants were contacted regularly between the four and eight week assessments to check how they were progressing with the study. This was also to improve the relationship between the researcher and patient (Vermeire & Hearnshaw, 2001).

Despite patients in both groups being advised by the University of Portsmouth researcher to continue with standard care, it was identified that not all patients followed the standard care recommendation and some patients did not receive the same standard care. Ninety percent of the participants in the bra prescription group wore their prescribed bra at least a couple of times per week (30%) or every day (60%). Previous research has reported average adherence to be around 50% for studies with medication as a treatment and around
10% for lifestyle interventions (Haynes et al., 2002). The adherence in this chapter is therefore considered to be high, although it would be advantageous to the outcome of the study if all participants wore the prescribed bra every day. Thirty percent of participants in this group purchased new bras in their newly fitted size. Although adherence to the prescribed bra was high, adherence to the standard care within the bra prescription group was much lower than the standard care group. This is problematic as the bra prescription should supplement and not replace the standard care provided by clinicians. The bra prescription itself did not have a negative effect on breast pain for any participant, but the outcome may have been improved had the participants continued with the other aspects of standard care as well. An additional problem with the standard care was that it was not consistently applied and not all patients received the same advice. This meant the standard care group did not have a consistent treatment which could have affected the overall outcome of the RCT.

Rather than having a bra prescription, the patients within the standard care group were recommended to get a professional bra fitting. Over a third had taken up advice to get a bra fitting by four weeks, however, this increased to 63% by eight weeks. Perhaps the remaining participants had difficulty in identifying where these services are provided and perhaps clinicians would be prudent to provide each patient with a list of where these services can be obtained. Although, research has suggested that a bra fit is beneficial to breast pain, patients continue to have difficulty finding an appropriate bra post-fitting (Woollett et al., 2012). Due to this, it may be more beneficial to implement this bra intervention within the clinic environment or as a referral service where clinicians can directly refer patients to get an appropriate bra.

Clinicians could then be confident that this aspect of standard care is being followed. Interestingly, only one patient was actually refitted into a different bra size within the standard care group. This is compared to the patients who were initially recruited into the bra prescription group (n = 11) where 91% (n = 10) were in a poorly fitting bra. This could indicate problems with the bra fitting services being provided by retailers as many still offer the traditional method of bra fitting using the tape measure method, which has been found to be inaccurate (White & Scurr, 2012).

Compliance with the use of topical ibuprofen gel was also low for both groups (sections 6.4.4). No patients within the bra prescription group reported using the gel at any point over the eight week period; however 40% of the patients reported not being recommended to use ibuprofen gel. Within the standard care group only two patients reported using the gel at four weeks, and three at eight weeks; 50% of those who did not use the ibuprofen gel reported that the use of it was not recommended. This is concerning as it suggests there
may be a discrepancy in standard care advice within the clinic across clinicians and as a result a different care is provided to women with breast pain. It is however important to acknowledge that the standard care all participants should have been provided was written within the breast pain leaflet (“Breast pain,” 2010). All patients therefore will have received the same information in written form, it may be that the verbal information provided by clinicians varied. It is also possible, between the time of the patient’s appointment and the questionnaires, they may have forgotten all of the advice given. In this study, compliance with the topical ibuprofen was mixed (0% in the bra prescription group and 62% in the standard care group) but interestingly, 20% in the bra prescription group and 13% in the standard care group did not use the topical ibuprofen because they did not feel it would help their condition. This is important information for the clinicians within the QA Hospital as their guidance for using the topical ibuprofen may need amending. A study investigating the effect of Non-Steroidal Anti-Inflammatory Drug’s (NSAID’s) on breast pain found that they were more effective than EPO over a three month period. This indicates the effectiveness of this part of the standard care, and this should be promoted more by clinicians so patients are aware of the benefits of using the topical ibuprofen gel.

All of the standard care group (100%) used the Breast Cancer Care leaflet on breast pain (“Breast pain,” 2010) demonstrating good adherence to this part of the standard care. Although a lower number (30%) in the bra prescription group used the leaflet. Perhaps the standard care group had a greater need to refer to the leaflet as they did not receive a bra prescription. Equally, the bra prescription group may have not seen a need to use the leaflet as they had a bra prescribed, replacing their need for further information.

Patients were asked about lifestyle factors (such as changes to medications, diet and fluid habits and exercise habits) to assess whether these factors could have been confounding variables in their results. Five patients (50%) within the bra prescription group increased their volume of exercise over the eight weeks. Out of these five patients only one saw a reduction in breast pain over the eight weeks, although this was not clinically significant. The remaining four patients reported no change in breast pain intensity (n = 1), or an increase in breast pain intensity (n = 3). Research has determined that excessive breast movement during exercise can cause an increase in breast pain (Scurr et al., 2010), so it could be suggested that their increase in pain may have been a result of an increase in exercise. It is unknown whether the patients in this study used a sport bra whilst exercising. It is possible that these patients were not wearing a sports bra and if they were not, they may have experienced increases in their breast pain. Potentially, these patients needed a prescription for a sports bra as well as an everyday bra. However, 50% of the patients within the standard care group also increased the amount of exercise they completed with one
Evaluating the bra intervention

patient reporting an increase in breast pain, two reported a decrease of 1 point on the NRS scale (not clinically significant) and one reported a decrease that was clinically significant (decrease of more than two points on the NRS) so this link is therefore unclear. Exercise has previously been associated with improvements in the QoL of breast cancer sufferers (Bicego et al., 2008), so it could be suggested that increases in exercise may have also contributed to the improvements in QoL seen in the breast pain patients in the current study. One patient within the bra prescription group reported she had started a weight loss programme. The patient did not specify whether she had removed or reduced certain food groups from her diet, but it has been previously speculated that a healthier diet and a reduction in some food or drink, such as caffeine could help to reduce breast pain (meta-analysis completed by Smith et al., 2004). Diet change is also recommended in the Breast Cancer Care leaflet for Breast Pain (“Breast pain,” 2010) (given as part of the standard care) and on the NHS choices webpages (“Cyclical breast pain - Treatment,” 2012). However, for this patient, no change was seen in her breast pain intensity, indicating this change did not influence her breast pain. Previous research has produced mixed results suggesting there may be no effect of a healthier diet/supplement intake on breast pain (Brennan, Houssami, & French, 2005; Vaidyanathan et al., 2002). Three patients in the standard care group reported adopting a healthier diet over the eight weeks, however two of these patients reported an increase in breast pain intensity and one saw no change in breast pain, indicating that this did not have an effect on breast pain.

In both groups, one patient started taking EPO for their breast pain. Evening primrose oil has been suggested to improve breast pain, but there are mixed results (Blommers et al., 2002; Pruthi et al., 2010; Qureshi & Sultan, 2005). The patient within the bra prescription group reported an increase of 1 point for her breast pain intensity and the patient within the standard care group reported a reduction of 1 point showing minimal influence of EPO. Additionally, two patients within the standard care group reported using pain medications (paracetamol and ibuprofen) during the study, which could have contributed to the greater reduction in breast pain intensity for the standard care group. However, further inspection showed that these two patients reported an increase in breast pain, (+1 over the eight weeks n = 1) or reported an initial increase that reduced back to baseline (n = 1, +1 four weeks but dropped by one point by eight weeks). Only one patient within the bra prescription group reported stopping her contraceptive medication during the course of the study but she saw no change in her breast pain intensity. Breast pain is a possible side-effect of contraceptive medication as it increases the level of oestrogen in the body (Smith, Pruthi, & Fitzpatrick, 2004). Reducing or eliminating the level of oestrogen is reported to have a positive effect
on breast pain (Smith et al., 2004) but mixed findings have been reported for contraceptives containing predominantly progesterone (Smith, Pruthi, & Fitzpatrick, 2004).

7.7 Bra prescription session

The five-point best fit criteria was used to assess each bra tested. Additionally, a ranking of each bra tested across the KPI’s that were assessed (comfort, support, fit and aesthetics) were given. Finally, it aimed to investigate individual patient’s breast position within their own bra and how it compared to each of the bras they were tested in.

Research has reported that between 70 and 100% of women are wearing incorrectly fitting bras (Greenbaum et al., 2003); this is despite bra fitting services being available freely in many lingerie stores. Women with larger breasts typically struggle to find well-fitting bras due to the size and shape of their breasts, and are less likely to use professional bra fitting services due to embarrassment and self-consciousness (Greenbaum et al., 2003). Within this study, 10 out of 11 of the patients were wearing a poorly fitting bra. A bra was prescribed to 10 out of 11 patients; one patients’ own bra fitted and performed better overall than the selected range of bras from Chapter Three.

From the selected bras (Chapter Three); not all of the bras met the five point best fit criteria for each participant, demonstrating how bra designs vary between and within brands and manufacturers, and emphasising the difficulty women face when purchasing bras. Chapter Two identified that a lack of availability and choice, were issues for women but also they reported large variation between retailers. Hardaker and Fozzard (1997) reported that large numbers of bras sizes exist to cater for a variety of body sizes and shapes. Only one participant fitted in all of the bras (selected in Chapter Three), despite the variation in sizes. One patient saw a two cup size difference in the bras that fitted, further indicating that patients should be educated on good bra fit rather than focussing on absolute bra size.

The second aim of this section was to assess the performance of the selected bras (Chapter Three). The bra that performed the best across the four KPI’s varied for each patient. Bra 3 for example, only fitted four patients, yet performed the best for two patients, whereas bra 6 fitted in almost all patients (n = 9) yet was only prescribed to one patient. P1’s highest performing bra was bra 3, yet this bra was ranked 5th for P6. This shows that although it is important for the bras to fit, overall performance of the bras may still vary.

For the individual KPI’s (comfort, support, fit and aesthetics) there were mixed results as to which bras performed best. Only one participant’s prescribed bra ranked top for all four KPI’s. Comfort was ranked highest in the prescribed bra for six out of 10 patients, support for five out of 10 patients, fit for eight out of 10 patients and aesthetics five out of 10 patients. This is interesting as fit and aesthetics were weighted identically, but demonstrates that
patients were able to identify a good fit, even if they did not like the aesthetics of the bra as much.

Penn (1955) reported a vertical suprasternal notch to nipple distance of 20 to 21 cm (8 to 8.5 inches) as the most aesthetically correct. Across the selection of bras, on average the patient’s breast positions were more aesthetically pleasing (projected, separated and lifted) compared to their own bras. The literature suggests that lifting, or elevating the breasts helps to reduce movement-induced breast pain in women with larger breasts (McGhee & Steele, 2010a), therefore this change in position is likely to be a positive change for patients within this study. Compression is also recommended for reducing movement-induced breast pain (McGhee & Steele, 2010a), as it flattens the breast tissue towards the chest wall limiting the excessive movement of the breasts. The breasts on average were projected in this study which may not have aided the patient’s breast pain, but could have improved the level of adherence to the study as the position of the breasts was more aesthetically pleasing.

7.8 Comparison of the prescribed bra to the intervention outcome

Support is one of the main factors that is reported to reduce movement-induced breast pain (Mason et al., 1999; Scurr et al., 2010). P11 saw improvements across all outcome measures (PGIC, breast pain intensity and QoL). This patient had a bra prescribed to them that was less supportive than the other bras they tested. This indicates that for this patient support was not the KPI that influenced the results the most. As compression and elevation of the breasts have also been associated with lower levels of breast pain (McGhee & Steele, 2010a). The bra prescribed to P11 provided lift, but was not compressive when compared to her own everyday bra. Current biomechanics literature reports that as support increases, breast pain decreases (Mason et al., 1999; Scurr et al., 2010), and this is due to a reduction in breast movement. The literature is often based on running trials or other vigorous activities thought and the clinical breast pain population do not necessarily need this level of support during activities of daily living. The three participants (P2, P4 and P11) who had clinically significant improvements in breast pain and also saw clinically significant improvements in their PGIC scores, were prescribed bras that lifted their breasts but did not compress them. Their prescribed bras ranked; 2nd (P2), 3rd (P4) and 6th (P11) for support. All of these participants also saw clinically significant improvements in the MCS and some saw improvements in the PCS. Perhaps lift is therefore an important factor to consider for a bra prescription rather than overall support.
7.9 Cost benefit analysis

The final aspect of the feasibility assessment is to perform a cost benefit analysis. Again due to the limited sample size obtained, this cannot be completed fully.

For the bra prescription session to run, each of the six bras chosen within Chapter Three had to be purchased in each of the sizes described in the inclusion criteria. This was four under band sizes and four cup sizes (16 sizes per bra style x six bra styles = 96 bras total) with an initial cost of £1856. Two bras per participant were then purchased for each of the patient within the bra prescription group (total cost = £316). Therefore, the total spend on bras was £2172. If the full 100 participants were recruited into the bra prescription group, this cost is estimated as £5016 (£3160 for the prescribed bras and £1856 for the bras to use in the bra prescription session). There were no additional costs for the standard care treatment.

Additional costs for the study are for the researcher time to; recruit patients, run the bra prescription session, analyse the data and monitor the participants over the eight week intervention. If this study were implemented as a full referral service, these costs would need to be considered along with the facilities and equipment purchasing and maintenance costs.

The current standard care provided by the QA Hospital in Portsmouth is of little cost. Patients are encouraged to wear a properly fitting bra that has been professionally fitted and to use topical ibuprofen, neither of which is provided by the clinic. Patients are provided with the breast pain leaflet (“Breast pain,” 2010) but these are free to order. The bra prescription itself therefore will add a significant additional cost to the current standard care provided to patients with benign breast pain. The cost-benefit of the bra prescription cannot be fully attained as the sample size was limited.

7.10 Conclusion

The procedural aspects of the bra intervention ran as planned. The outcome of the study was not as strong as expected, based on the positive outcomes seen in previous studies (Hadi, 2000; Wilson & Sellwood, 1976; Woollett et al., 2012).

The key finding of the bra intervention was a statistically significant improvement in QoL within the bra prescription group demonstrating a benefit of this bra intervention. Despite positive changes in bra fit, prescribing bras based on the four KPI’s (comfort, support, fit and aesthetics) resulted in no statistically or clinically significant improvements in breast pain intensity across the groups.

Despite few statistically significant findings, the patients within the bra prescription group were provided with bras that were more appropriate than the current bras. It is therefore a
recommending that this intervention should be developed further as it ensures patients are wearing appropriately fitting bras and there is no negative impact on breast pain, yet there is a positive improvement in QoL.

The sample size was the main limiting factor within this study, it is therefore important to investigate this further, as this may have limited the outcomes achieved. To improve the sample size within the study there needs to be an investigation into why the recruitment and retention for the intervention study were low. Firstly, the prevalence of breast pain (as the only symptom) may have been lower than anticipated or the inclusion/exclusion criteria may have been too restrictive, limiting the ability to recruit patients present in the clinic. Additionally, the interest in the bra intervention itself may have been low, this needs to be investigated and motivational factors in this type of intervention should be examined. The interest in the bra intervention should then be compared with alternative cohorts, to identify whether the cohort chosen within this thesis (women with larger breasts who were experiencing breast pain) was appropriate. Identifying interest should be completed in the form of a qualitative study as this will allow for opportunities and barriers to participation to be investigated (Campbell et al., 2007). The next chapter in this thesis will therefore aim to assess the interest in the bra intervention (specifically the prescription of a bra) and barriers to it, amongst clinic patients with and without breast pain. It will also investigate whether clinic patients are interested in this type of intervention. Furthermore, it is important to identify the type of advice patients would like to receive, as this could be used to further develop the intervention to make it more attractive to patients.

The decision to choose an RCT trial design was appropriate, albeit that recruitment did not meet the required numbers, as it is designed to remove bias. Although, a preference trial may have improved recruitment (Torgerson & Sibbald, 1998) and may have encouraged more patients to participate. The RCT allowed for the identification of problems in recruitment and retention and these should be investigated further (Brewin & Bradley, 1989). It is therefore a conclusion of this chapter that the bra intervention should not be implemented at this stage, further evaluation should be conducted prior to continuing to develop the intervention.
8 Chapter Eight: The prevalence of breast pain in breast clinic patients and the perceived value of a bra prescription service.

8.1 Introduction

The main limiting factor of the bra intervention (Chapters Six and Seven) was the sample size. It is important to investigate this further, as this may have limited the outcomes achieved. The areas to evaluate are the;

- Prevalence of breast pain within the clinic
- Whether the inclusion/exclusion criteria were too restrictive for the recruitment of patients
- Interest in the bra intervention (specifically the prescription of a bra)
- Barriers to participating in the bra intervention, amongst clinic patients with and without breast pain
- Advice patients would like to receive within the bra intervention

Previous literature reports breast pain prevalence to be 52% in the UK general population (Scurr et al., 2014) and it being prevalent in the majority of patients at breast clinics (Tavaf-Motamen et al., 1998), although a recent study identified that 13% of referrals to the Nottingham Breast Institute related to breast pain that could be treated in primary care (Sawyers, Laking, & Gutteridge, 2018). However, only 2% of the clinic (Chapter Six) were assessed for eligibility.

Additionally, patients were required to be a larger cup size (DD and above) and free from any other breast conditions, but, perhaps a larger proportion of patients are of a smaller cup size or have breast pain in combination with another breast condition (e.g. a lump or a cyst).

Additionally, 19% of patients who were assessed for eligibility declined to participate. Although the reasons for this cannot be determined post-study, assessing the interest in the service within the clinic may identify whether 19% of patients within Chapter Six is representative of the general interest in the service. A comparison should also be made with patients who are not experiencing breast pain to assess whether their interest is at a similar level to patients with breast pain. It is possible that patients may have felt their current bras were appropriate and consequently they may have felt little need to participate in the bra intervention. This is an important factor to investigate as a proxy for interest in the bra intervention.

The study should also investigate why the dropout rate was high for each group; 33% in the bra prescription group and 50% in the standard care group. Previous studies investigating treating breast pain patients using bras had drop-out rates of 4% (Wilson & Sellwood, 1976).
and 9% (Woollett et al., 2012) however these were single group design studies. Two studies which had control and intervention groups examining the effect of Pilates (Gladwell, Head, Haggar, & Beneke, 2006) and a fitness programme (Frost, Klaber Moffett, Moser, & Fairbank, 1995) on lower back pain had 20% drop out in the intervention group and 41% drop out in the control group (Gladwell et al., 2006) and 12% in the intervention group and 13% in the control group (Frost et al., 1995). This is lower than the groups within the bra intervention study.

The reasons given for drop out for both groups in this programme of work included a lack of time to participate or unable to commit (n = 3), a lack of suitability for the study (n = 1) or that participants provided incorrect contact details (n = 2). The remaining patients who dropped out (n = 8) were lost to follow up. An investigation into the barriers to the service would help to identify the reasons for not participating in the bra intervention if it were to run as a service for patients (Campbell et al., 2007). This information could also be used to determine areas of the bra intervention that could be altered to improve recruitment and minimise drop-outs in the future.

8.1.1 Aims

1. To investigate the prevalence of breast pain in patients visiting the New Patient Breast Clinic at the QA Hospital
2. To investigate whether patients experiencing breast pain are interested in a bra prescription service run by the Research Group in Breast Health
3. To understand whether patients (with and without breast pain) perceive their current everyday bras to be appropriate
4. To identify the barriers that would prevent patients experiencing breast pain from using the bra prescription service
5. To understand whether patients who are not experiencing breast pain are interested in attending a bra prescription service run by the Research Group in Breast Health
6. To understand the barriers that would prevent patients who do not experience breast pain from using the bra prescription service

8.2 Methods

8.2.1 Study Design

This was a descriptive study sampling patients attending the New Patient Breast Clinic at the QA Hospital using a convenience sample method. Patients were able to opt out of completing the surveys.
8.2.2 Patients

The inclusion criteria were: female, aged 18 years and over, willing and able to give informed consent for participation in the study and attending the New Patient Breast Clinic at the QA Hospital. Patients were excluded from the study if they were unable to read or understand English fluently to complete the survey (self-exclusion by patients). Patients were also excluded if they were suspected of having breast cancer. These last criteria were put in place as patients who are suspected of having breast cancer will be sent for further tests and may be highly emotional, therefore the timing of the survey would not be appropriate.

8.2.3 Development of the survey (Appendix K)

The survey included demographic information; age, bra size, menopausal status and a question indicating whether the respondent had previously had breast surgery. Due to the purpose of the survey information also had to be collected on the reason for visiting the clinic (to identify the number of patients attending for breast pain), and breast pain (as some patients may experience breast pain but not be attending the clinic for this purpose).

The survey assessed interest in finding a well-fitting and supportive bra and then specifically asked about interest in the bra prescription service itself. This was to identify whether there was any difference between these as this may indicate whether the bra prescription itself was a deterrent to participating. It was also important to understand whether the patients currently wear a bra, and whether they feel their bra fits or if they have any problems with the bra, and to understand the barriers to this type of service.

The question format was varied to maintain interest from the respondents as this has been suggested to prevent answers being based on repetition (Bradburn, Sudman, & Wansink, 2004). Both open ended and closed questions featured in the survey as well as scale questions (using the NRS 0-10, 11 point scale used throughout this thesis), dichotomous questions (yes/no) and multiple choice questions. For the barriers and advice questions both inductive and deductive methods were used to identify the items to include in these questions (Hinkin, 1995). For the barriers, it was suspected that the time commitment required for patients was a factor for not participating, therefore this was included as well as the location of the prescription (University of Portsmouth). Additionally, as the survey would identify whether participants feel that their current bras fit, this was also included as a barrier. Additional response options on potential barriers were included based on anecdotal feedback during the intervention study and Chapter Two of this thesis. For the advice within the bra prescription service, the topics presented were based on the expertise of the Research Group in Breast Health who would be running the bra prescription service.
For both questions an open ended option was also presented for patients to add any additional barriers to the bra prescription service or advice they would like to receive during the service.

Krosnick and Presser (2010) reported a number of factors to consider when sequencing questions and laying out the survey. Questions that are at the beginning of the survey should be pleasant to answer but should also address the topic of the survey. Therefore, it was decided that the patient’s reasons for attending the clinic and the breast pain questions were asked first. This question had a write-in response to allow patients to report if they were experiencing multiple symptoms. Although these questions may be more sensitive, they are imperative to the purpose of this study and were therefore asked first (Bradburn et al., 2004). Following the breast pain questions, participants were asked about their bra wearing habits, bra size and whether they had any problems with their bras. This led on to the question about their interest in the bra prescription service, any barriers to it and the advice they would want in the bra prescription session. The questions were grouped by topic, and allowed for the patients who did not wear bras and did not plan to wear bras in the future to be filtered out early on in the survey, minimising any irrelevant questions (Krosnick & Presser, 2010). Finally, participants were asked demographic questions, including their age and whether they had had any surgery.

The survey was kept to two sides of A4 paper to minimise the burden on participants and the questions were laid out in two columns and were not split between pages (Frazer & Lawley, 2000). Additionally, the survey was on headed paper to ensure it looked authentic and official (Gillham, 2007) and to encourage a good response rate.

Face validity was assessed as the survey was reviewed prior to ethical submission by a clinician with expertise in the area, who worked within the New Patient Breast Clinic at the QA Hospital. The clinician reported that the survey was suitable.

8.2.4 Procedures

Favourable ethical approval was obtained. This survey had no additional consent form or participant information sheet, instead a paragraph was added to the top of the survey describing the study and informing the patients that by completing the survey they were providing consent to take part. The survey itself was anonymous and no identifiable information was collected. All patients who were offered the survey were informed that their participation was voluntary and there was no requirement for them to participate.

The survey took approximately five minutes to complete dependant on the level of detail given by patients in the open questions. The survey had 15 questions. The question type and language was made simple to enable all patients to complete the survey. As the surveys
were anonymous, once completed the surveys could not be retracted or removed from the study. The study ran for six weeks from the 25th April 2016. All eligible patients were offered the survey following their consultation within the clinic. Patients who complete the survey were asked to leave the completed survey in a secure box provided in the department. Surveys were collected by the researcher and all study data were entered manually onto an Excel (Microsoft Office 2013) spreadsheet, the study data were coded where necessary (see section 7.2.6) by the same researcher to ensure consistency. Surveys were assigned a survey number during this process to ensure the electronic records could be matched to the paper records. Only the study team had access to the paper surveys and electronic spreadsheet. Electronic files were kept on a password protected hard drive and paper surveys in a locked filing cabinet.

8.2.5 Sample Size
A response rate lower than 65% is unlikely to be considered for publication in the British Medical Journal (“Is The BMJ the right journal for my research article?,” 2018). Therefore, this rate was considered appropriate for this study. The response rate for the study was calculated as;

\[
\text{Response rate} = \frac{\text{number of post-consultation surveys}}{\text{number of patients attending the clinic during the study duration}} \times 100.
\]

8.2.6 Data Analysis
All data were coded during data entry. Yes/No questions were coded as 1 or 2 respectively. Open-ended questions were assessed using an inductive content analysis by a researcher who had previous experience of this method. Barriers to attending the bra prescription service were analysed using frequency analysis and reported as percentages. Demographic data were reported using means, modes, ranges and percentages where appropriate. Data were analysed as a whole and to assess whether the inclusion criteria for the bra intervention study were appropriate, data were also split into the cohorts of patients who do or do not experience breast pain and patients who were a D cup and below or DD and above UK bra cup size. A Chi-Squared or binomial test for proportions was used to compare the results between different patient cohorts; breast pain patients versus non breast pain patients and patients who were a D cup size and below compared to DD and above bra cup size. The alpha value was set to \( P = 0.05 \). The numbers of patients (n) who completed each question on the surveys are reported in the results section.
8.3 Results

8.3.1 Participants

Over the six weeks of data collection, 988 patients were seen in clinic, with 256 surveys completed (response rate of 26%). Two surveys were removed from the sample; one as it was completed by a patient who was under 18 (therefore not meeting the inclusion criteria) and another as it was unusable. This left 254 useable surveys.

The average age of the patients (n = 233) who responded was 41 ± 13 years. Bra size was self-reported by 184 patients. Modal self-reported bra size was a 36B, with a range of 28 to 46 under band size and A to JJ cup size. Two patients (1%) did not specify their bra cup size and there was a larger proportion of patients who were a D cup size and below (n = 113, 61%) compared to patients who self-reported to be a DD cup size or above (n = 69, 38%).

The most common reason given by patients for attending the clinic was due to a breast lump (Table 8.1).

Table 8.1: Patients reasons for attending the clinic given on the survey

<table>
<thead>
<tr>
<th>Symptom</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lump</td>
<td>127</td>
<td>50.0</td>
</tr>
<tr>
<td>Breast pain</td>
<td>45</td>
<td>17.7</td>
</tr>
<tr>
<td>Breast pain and lump</td>
<td>37</td>
<td>14.6</td>
</tr>
<tr>
<td>Nipple discharge</td>
<td>5</td>
<td>2.0</td>
</tr>
<tr>
<td>GP referral</td>
<td>4</td>
<td>1.6</td>
</tr>
<tr>
<td>Inverted nipple</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>Underarm pain/swelling</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>Follow up due to previous history/genetics</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>Cysts</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Swelling</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Abscess</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Breast pain and discharge</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Lump and discharge</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Dimpling</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Breast pain and itchy nipple</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Itchy breast</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Hardened tissue</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Rash</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Breast size and pain</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Fully body check</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Breast pain and cysts</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Shoulder pain</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Lump and other sensation</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Lump and shape change</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Missing</td>
<td>5</td>
<td>2.0</td>
</tr>
<tr>
<td>Total</td>
<td>254</td>
<td>100.0</td>
</tr>
</tbody>
</table>
Eighteen percent of patients reported attending the clinic with breast pain as their only symptom. Overall 87 patients (34%) were attending the clinic with breast pain as their only symptom or in conjunction with another symptom. Overall, 158 patients (62%) reported experiencing breast pain in the separate question (Do you experience breast pain?). Modal breast pain intensity, across all patients experiencing breast pain, was 3 out of 10 (n = 157) (Figure 8.1). For patients reporting with breast pain as their only symptom (17.7%) there was a bimodal intensity of 6 and 8 out of 10 (n=41) (Figure 8.1). For patients reporting with breast pain plus another symptom (16.6%) the modal intensity was 7 out of 10 (n=37) (Figure 8.1).

![Bar chart](image)

**Figure 8.1:** Breast pain intensity reported by symptomatic patients at the New Patient Breast Clinic (n=157).

Thirty-four patients (13%) had previously had breast surgery. Types of surgery reported were: benign lump removal (n = 15), breast enlargement or reduction (n = 9), cyst removal (n = 3), cyst drainage (n = 1), DIEP reconstruction (n = 1), bilateral mastectomy (n = 1), abscess removal (n = 1) and nipple removal (n = 1).

Two hundred and forty-six patients (97%) were currently wearing a bra, two patients (1%) were not wearing a bra but one of these patients was planning to wear a bra in the future. The remaining patients did not answer this question. Two hundred and twelve patients (84%) reported that they felt they were wearing well-fitting and supportive bras. One hundred and eighty-six patients (73%) did not feel they had any problems with the bras they currently wear, and 51 (20%) reported they did have problems (Figure 8.2).
8.3.2 Interest in finding a well-fitting and supportive bra

Forty-four percent (n = 112) of patients were interested in receiving help to find well-fitting and supportive bras, 54% (n = 138) were not interested and 2% (n = 4) did not answer the question. There was no significant difference between the number of those interested versus not interested in receiving help (P = 0.114). Splitting the responses into patients who were experiencing breast pain versus those who were not, resulted in no significant differences (interested: breast pain; n = 74 (46%), no breast pain; n = 37 (40%); not interested: breast pain; n = 82 (51%), no breast pain; n = 57 (60%); χ² = 1.549, P = 0.238, Cramer’s V = 0.79). Bra cup size also had no significant effect on interest in receiving help (interested: D>; n = 54 (48%), DD<; n = 32 (46%); not interested; D>; n = 58 (52%), DD<; n = 37 (54%); χ² = 0.58, P = 0.879, Cramer’s V = 0.18).
8.3.3 Interest in Bra Prescription Service

Patients were then given a brief description of the bra prescription service that the University of Portsmouth could provide. One hundred and eight patients (43%) said they were interested in the prescription service, 139 (55%) were not and seven (3%) did not answer this question. Eighty-six patients (77%) who were interested in receiving help in finding well-fitting and supportive bras were also interested in the prescription service. There was no significant difference between the proportion of all patients interested in the bra prescription service compared to those who were not (Table 8.2) \( (P = 0.560) \).

**Table 8.2:** Comparison between cohorts who were interested or not interested in the prescription service

<table>
<thead>
<tr>
<th>Group</th>
<th>Interested in the bra prescription service</th>
<th>Not interested in the bra prescription service</th>
<th>( \chi^2 )</th>
<th>( P )</th>
<th>Cramers V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast pain versus no breast pain</td>
<td>Breast pain; ( n = 74 ) (30%), No breast pain; ( n = 33 ) (13%)</td>
<td>Breast pain; ( n = 81 ) (33%), No breast pain; ( n = 58 ) (24%)</td>
<td>3.074</td>
<td>0.085</td>
<td>0.11</td>
</tr>
<tr>
<td>D&gt; versus DD&lt;</td>
<td>D&gt;; ( n = 49 ) (28%), DD&lt;; ( n = 34 ) (19%)</td>
<td>D&gt;; ( n = 59 ) (33%), DD&lt;; ( n = 35 ) (20%)</td>
<td>0.258</td>
<td>0.645</td>
<td>0.38</td>
</tr>
</tbody>
</table>

8.3.4 Barriers to using the Bra Prescription Service

Two hundred and seven patients (82%) provided reasons as to what might stop them using the prescription service (Figure 8.3). Overall the largest barrier to the service was "I would find it difficult to find time to attend this service". This was also the highest barrier for patients with breast pain. For the patients who were not experiencing breast pain the largest barrier to participating was 'I fit in the bra I currently wear'.
Figure 8.3: Barriers to patients using the bra prescription service

Other reasons suggested by patients as to why they would not use the services are shown in Table 8.3.

Table 8.3: Additional reasons suggested by patients as barriers to using the bra prescription service

<table>
<thead>
<tr>
<th>Other reasons suggested by patients</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work/time commitments</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>Cost/money factors</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Other bra fitting services used</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Prefer to get advice from somewhere else (Rigby and Peller/Doctors surgery)</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Location/distance</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Bra fit is fine but finding a bra is difficult</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient confident at fitting herself</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Hormonal medical condition would not be helped by a bra</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient does not want to be observed</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient does not feel a prescription is necessary to find a bra</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient is self-conscious</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient feels it is difficult to change women’s opinions on bras and fit</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>New bras are not needed</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>
8.3.5 Advice patients would like to receive

One hundred and eighty-four patients (72%) reported the types of breast/bra advice they would like if they attended a bra prescription service (Figure 8.4). The top three categories patients would like advice on were; bra fitting, what happens to the breast as they age and what bras should they not be wearing. Additional topics suggested by patients included; what is normal [for breasts] (n = 1, 1%), how to examine breasts (n = 1, 1%), exercises to strengthen surrounding muscles (n = 1, 1%), bras to wear after mastectomy (n = 1, 1%) and have badly fitting bras caused any damage in the past? (n = 1, 1%).

![Figure 8.4: Types of advice wanted by patients within the clinic](image)

8.4 Discussion

This study aimed to understand the prevalence of breast pain within the New Patient Breast Clinic at the QA Hospital and to understand the interest and barriers to using a bra prescription service for sufferers of breast pain and the wider patient cohort. The context is important when designing an intervention, particularly the characteristics of the population (Campbell et al., 2007).

The reported prevalence of breast pain in this study was 62% of patients. This is higher than the reported 52% of women in the UK general population who report experiencing breast pain (Scurr et al., 2014). Despite this value, only 18% of patients were attending the clinic with breast pain as their only symptom. This is higher than a recently reported
prevalence of 13% in a Nottingham Breast clinic (Sawyers et al., 2018) although this represents breast pain that could be treated effectively in primary care. Even by incorporating those patients who are attending the clinic for breast pain plus another breast condition, this value only increases to 34% of clinic patients. This may indicate why there was a low sample obtained in the previous intervention study. However, if 18% of the previous sample (n = 3251) were assessed for eligibility this would have equalled 575 patients when in reality only 64 were assessed for eligibility. This indicates that there should have been a sufficient pool of patients for the bra intervention study (Chapter Six).

Increasing the criteria to include patients who had breast pain plus an additional breast condition may have doubled the numbers of patients available to the study, although results may have been skewed due to confounding factors associated with the additional breast condition. The sample within this survey study also reported their breast pain intensity on average to be three out of 10 (modal response) which is lower than the clinically significant level for pain (Ader & Browne, 1997) and may suggest why a half of patients experiencing breast pain were not attending the clinic for this reason. However, it is important to note that those who were attending the clinic for breast pain as their only symptom or reported breast pain plus another symptom were experiencing a clinically significant level (>4 out of 10) of breast pain. This is also important for context as it shows that although breast pain was being experienced, the severity of pain was low (Campbell et al., 2007).

Another factor that may have influenced recruitment for the bra intervention study (Chapter Six) was breast size. Within this survey sample there were a higher number of patients who self-reported to be a UK <D bra cup size (61%, compared to 38% reporting to be DD and above). Even if this proportion of patients with a DD and above bra size were recruited during the bra intervention, it should have resulted in 215 patients. Larger breast sizes were chosen due to research suggesting these women have greater difficulty finding appropriate bras because of the size and shape of their breasts (Greenbaum et al., 2003). It is also likely that the patients in this study incorrectly reported their bras size, as 91% of the bra prescription group in the Chapter Six were wearing incorrectly fitting bras. Therefore, there may be more patients within the D cup and below cup size range from this study who would actually be a DD cup size or above.

Inclusion criteria from the bra intervention study (Chapter Six) had to be met prior to patients consenting to participate, and prior to consent the patients could not be randomised into the two groups. The only way to assess patients for their bra size would therefore have been to provide a bra fit when assessing eligibility (prior to consent). There are problems associated with this in terms of the study design. For the standard care group, patients were requested to follow the instructions of the clinicians/nurses and part of their standard care is that they
are recommended to get a bra fitting. Providing a bra fitting would mean the standard care group would receive an additional intervention and would in turn stop them from being a control group, they would instead have been a different intervention group. For the bra prescription group, there is the risk that once provided with a bra size for this study, patients may drop out of the study prior to the bra prescription session and use other bra fitting services elsewhere. The alternative would be to include women of all bra sizes. This was financially problematic for this programme of work as each of the bras available would have to be purchased in every size possible. Additionally, the availability of the bras in all sizes was also a problem. Some of the bras chosen during the bra selection (Chapter Three) were specifically for cup sizes DD and above and were not manufactured in the smaller cup sizes. It is also important to note that women with smaller cup sizes were not interviewed or involved in focus groups so their bra preferences may be different.

The likelihood of patients wearing the incorrect bra size is high, especially as retailers may still be using the traditional method of bra fitting where there may be errors of up to four cup sizes (White & Scurr, 2012). But despite this, 84% of patients who responded to the survey reported that they were wearing a well-fitting and supportive bra, and only 20% of patients reported having problems with their bras currently. This is lower than previous research which has found 59% of horse-riders experience bra issues and the 39% of breast cancer patients who reported experiencing exercise bra discomfort (184/466 patients) (Burbage & Cameron, 2016; Gho, Munro, Jones, & Steele, 2013).

Twelve eligible patients in the bra intervention study (Chapter Six) did not consent to participate in the intervention study. This could have been due to the patients feeling their bras were appropriately fitting, and not understanding the additional benefits that could occur based on the other three KPI’s. Also, this percentage may explain why some patients within the standard care group did not take up the bra fit recommendation, as it is possible they did not think their bras were an issue.

Previous research in physical activity interventions has reported that patients will only make positive changes to their behaviour if they understood their level of physical activity is inadequate (Ronda, Van Assema, & Brug, 2001). This can be linked with the findings of this thesis, as it is possible that unless the patients are aware their bras are inadequate, they may not participate in a bra intervention to help with their breast pain. Two hundred and forty-seven patients (96%) reported that they were currently wearing bras or were planning to wear a bra in the future, indicating that a lack of interest in the bra prescription service was not due to the patients not wearing bras in the first instance.
Between 40% and 50% of patients were interested in receiving help to find a well-fitting and supportive bra. Similar proportions were reported for those interested in the bra prescription service (between 34% and 50%). This is interesting as it demonstrates that the majority of patients in the clinic were not interested in the bra prescription service. It is possible that this relates to the high number of patients who felt they are wearing well-fitting and supportive bras, although it is unlikely that they all would have been. Previous research has identified the positive association between education and improving bra knowledge and fit (McGhee et al., 2010). It is therefore important that patients are provided with education on bra fit, as this will enable them to make informed decisions about their bras and they would be able to assess their own bra fit. This would be in addition to the standard care recommendation to get a professional bra fit.

As the interest in a bra prescription service was moderate to low, and dropout rates (Chapter Six) were high, the reported barriers to using this service are important to understand. Knowledge of the barriers to uptake of the bra prescription service will help to refine the bra intervention in the future (Campbell et al., 2007). The top four reported barriers for patients, regardless of whether they were breast pain sufferers, were the same; “I do not feel I need a new bra”, “I fit in the bras I currently wear”, “I would find it difficult to find time to attend this service” and “I am not worried enough about my bras to take this service up”. Aside from time, the other three top barriers relate to the bras that the participants are currently wearing, suggesting that patients feel they are wearing appropriate bras.

It is unsurprising that time was a reported barrier in this study as it was also reported by patients who dropped out of the bra intervention study. The location of the service was also ranked high (5th for all patients) and should be a consideration for this service. Perhaps the service should be adapted to run from the Hospital itself, as patients have already shown willing to travel there and it could offer an immediate place of referral for patients following their appointment. Also important, is that those patients who reported additional reasons for not using a bra prescription service reported that they would not use it due to other fitting services being used, or that they would prefer the advice to come from a doctor or a retailer. The experience of the researcher and the Research Group in Breast Health should be promoted more prior to the bra intervention, so that patients are aware of the expertise within the group and can be reassured they are receiving a high quality service.

Perhaps prescribing a bra is too restrictive for women even if it could improve their breast pain or QoL. This may be due to the small range of bras on offer during the bra prescription session. This is despite previous research indicating that patients found it difficult to find appropriate bras themselves following a bra fit (Woollett et al., 2012). It is likely that the majority of patients passing through the clinic were wearing incorrectly fitting bras, but
currently the patients do not feel that their bras are a problem. It may be that educating women on bras and breast health is the first step to changing perceptions and encouraging women to take responsibility of their own bras and bra fit. It could be suggested that because patients are having an issue with their breasts, the patients in this study are more likely to ensure they are wearing a well-fitting bra. However, this was not the case for the patients who took part in the bra intervention study (Chapter Six).

The four most reported topics patients wanted advice on were “bra fitting”, “what happens to the breast as I age”, “what bras should I not wear” and “the problems with poorly fitting bras”. Bra fitting was rated highest overall (over 50%) which is interesting considering 83% of patients reported wearing well-fitting and supportive bras. These topic areas could be delivered as part of a wider intervention or as a standalone educational project to improve patient’s knowledge in the areas of bras. It is important to know that some patients would not find the time to use the bra prescription service or would find the location of the University of Portsmouth difficult to access as this allows a more tailored intervention to be developed. To enable a wide cohort of patients to access education material; a leaflet, online webpages, a mobile application or lectures/seminars could be created or run in collaboration with the NHS to provide the clinical and scientific advice women want around the topics of bras and breast health. This would educate women on how to make an informed choice when purchasing bras but also may help women to identify when they are having issues with their own bras.

8.5 Conclusion

A high number of patients within this study experienced breast pain (62%), higher than the reported values within the UK general population (52%, Scurr et al., 2014). Despite this, only 18% were attending the clinic because of their breast pain, limiting the number of accessible patients for the bra intervention (Chapter Six. Increasing the cohort of patients to include those with breast pain and other conditions is not appropriate due to the confounding variables that this would introduce. This study identified the interest in the service is not significantly different between patients with smaller and larger breasts, which perhaps suggests the intervention should be open to all bra sizes, although this has cost implications. The main barriers to the bra prescription service were; 1 = “I do not feel I need a new bra”, 2 = “I fit in the bras I currently wear”, 3 = “I would find it difficult to find time to attend this service” and 4 = “I am not worried enough about my bras to take this service up” and these should be considered when further developing the bra intervention, particularly the attitude of patients towards their own bra fit and educating women on good bra fit. The main advice patients wanted from this service was bra fit advice. This could be included in the bra prescription service to ensure patients are educated and can make informed choices.
after the prescription. This service would be better than the standard care currently received by patients because they do not have to seek the professional bra fit services themselves. This chapter identified a high number of patients reporting that their bras were well-fitting and supportive, and this may indicate why interest was low. Perhaps women who are attending the breast clinic are more aware of their breast issues and as a consequence feel they have a greater awareness of breast and bra issues.

As a result, the next chapter in this thesis continues the evaluation phase of the intervention development. It will explore the interest in the bra prescription service for non-clinical cohorts. This could indicate a more appropriate cohort for applying the bra prescription service and provides a comparison of the levels of interest.
9 Chapter Nine: Interest in a bra prescription for non-clinical groups of women; a comparative study

9.1 Introduction

Chapter Seven concluded that the sample size was the main limitation to the bra intervention being effective. As a consequence, interest in the bra intervention and barriers to participation was investigated within the same clinic group. This chapter will assess the level of interest with alternative groups to ensure the bra prescription service is directed to the most appropriate group. It also allows us to determine whether the interest in the bra intervention and the barriers to participation differ, which may suggest that the clinical cohort are an unusual population.

Six new groups were reviewed for inclusion within the Chapter, these were; women who were pregnant and breast feeding, women recovering from breast cancer, women who had had breast surgery and age (young adults, middle-aged adults and older adults). Section 9.1.1 reviews the rationale for including these primary groups.

Adolescent girls were also considered for inclusion, however their level of interest in the bra prescription service would be less comparable than the other nine groups due to their age, they would need parental consent, and therefore their participation would be reliant on the parent’s level of interest on behalf of their child. Additionally, there is no current evidence to suggest breast pain can be reduced in adolescents by a bra. Therefore, adolescent girls were excluded.

Different ethnic groups were also considered. However, the literature reports that in Asian cultures breast pain prevalence can be as low as 5% compared to 52% in the UK general population (Muralidhar et al., 2016; Pirti et al., 2016; Scurr et al., 2014). It is difficult to attribute this difference to ethnicity alone as one suggested cause of breast pain is related to dietary and fluid intake (Smith et al., 2004), and the dietary and physical activity level differences between Western cultures and Asian cultures is evident, with Western cultures having a higher fat content and lower levels of physical activity (Salant & Lauderdale, 2003). Therefore, it could be suggested that dietary and fluid differences, and possibly sedentary behaviours, are the influencing factor for breast pain and not ethnic background. As there is no clear evidence to suggest breast pain is different between UK citizens with different ethnic backgrounds ethnicity will not be investigated within this study. Additionally, there is no research which suggests that different ethnic groups may have different bra requirements, although this is possible. Research has identified some difference in breast size dissatisfaction between ethnic groups; with Asian Americans reporting greater breast
Comparing interest in the bra prescription service in non-clinical cohorts

dissatisfaction than any other group, but there was no difference when breast size was controlled (Forbes & Frederick, 2008).

The primary groups for consideration in this study and comparison to the clinical cohort are:

- Pregnant/Breastfeeding
- Breast cancer
- Breast surgery
- Young adult (18 to 39 years)
- Middle aged adult (40 to 54 years)
- Older adult (55 years and above)

9.1.1 Rationale for the groups

9.1.1.1 Pregnancy and breastfeeding

Women who are pregnant or breastfeeding experience rapid breast changes which may subsequently affect the bras they wear. The breast undergoes remodelling with initial increases in breast size followed by a decrease in volume during lactation (Hassiotou & Geddes, 2013). The early stages of pregnancy and engorgement (increase in size) of the breasts during breastfeeding may also lead to breast pain (“Breast pain,” 2016; “Breast pain and breastfeeding,” 2016). Smith (2016) reports that breastfeeding pain can be attributed to a number of things, engorgement due to the increase in milk volume can be a factor. Non-wired/nursing bras are typically recommended by bra fitters for pregnant and breastfeeding women, but these need to be fitted correctly and the size needed may change frequently. Research has found that breastfeeding women find it difficult to find supportive sports and nursing bras to alleviate breast pain (Morris, Park, & Sarkar, 2017), making it likely that this group would be interested in the bra prescription service.

A bra prescription service does not have to be a one-off service. If this group were to take up the service they may be recommended to return to the service at certain points of the pregnancy process and then subsequently when they have given birth and need bras for breastfeeding. Women are recommended to get a maternity bra fitting at 12 weeks pregnant and for a nursing bra at 36 weeks pregnant (Mothercare, n.d.). Therefore, due to the anatomical changes and prevalence of breast pain that occurs during pregnancy and breastfeeding it is worthwhile investigating the interest in a bra prescription service within this group.

9.1.1.2 Breast Cancer

A review paper reported that some breast cancer survivors experience chronic pain following mastectomies, which negatively affects their QoL (Kaur & Jain, 2017). This may
Comparing interest in the bra prescription service in non-clinical cohorts

indicate an additional benefit of applying the bra prescription service to this group as Chapter Six identified that QoL can be improved following a bra prescription. Within the breast cancer population 36% of women report breast asymmetries (which may affect bra fit) and 42% report breast pain (Gho et al., 2014). Women with breast cancer may have a mastectomy and subsequently may choose reconstruction which may alter the size and shape of the breast. Some women may choose not to have reconstruction and may use a prosthesis, this may then require the women to use post-surgery bras which have a pocket to hold the prosthesis in place. There are limited bras available for women recovering from breast cancer and this may increase the difficulty in finding an appropriate bra to wear. Therefore, due to the additional breast issues these women experience and the smaller number of bras available, these women may benefit from a bra prescription service and therefore their desire for this service should be investigated.

9.1.1.3 Breast Surgery

Women who have had other types of breast surgery, for example, breast implants, breast reductions, preventative mastectomies or cyst removal may also benefit from a bra prescription service. Implants and mastectomies will change the size, shape and symmetry of the breasts therefore the women who have experienced both of these type of surgery may find they need new bras. This may be a difficult process as their bra needs will have changed. Ried, Armstrong, Sali and McLaughlin (2014) reported that women who have had implants may find they experience discomfort and asymmetries resulting from capsular contraction. Smith et al. (2004) reported breast pain affected those who had a mastectomy (31%), those who had a mastectomy and reconstruction (49%), those who had breast augmentation (38%) and those who had a breast reduction (22%), demonstrating the incidence of pain after surgery is high. The high levels of breast pain and potential bra sizes changes that occur within this group demonstrate the need to investigate interest in the bra prescription group for women who have had breast surgery.

9.1.1.1 Age

Research has determined specific bra preferences for older women (Risius et al., 2014) which are similar but not the same as the preferences identified in Chapter Two for women with breast pain and larger breasts. The bra prescription service prescribes bras based on preferences which are measured both subjectively and objectively. Comparing the results of Chapter Two and the study by Risius et al., (2014) there are preference differences between premenopausal versus mature women, which suggests that these groups have different bra needs. The difference in bra preferences may indicate that the level of interest in a bra prescription service may differ. To compare between different aged women, age
groupings need to be determined. Previous research developing physical activity interventions for different age groups used age bandings of; 18 to 39 years for a young adult, 40 to 54 years for middle-aged adults and older adults were aged 55 to 80 (Ziegelmann, Lippke, & Schwarzer, 2006). All three age bandings should be investigated to see if there is a difference in interest in the bra prescription service as age increases. Additionally, the predominant type of breast pain experienced differs by age. Younger women typically experience cyclical breast pain, which often presents itself in the third and fourth decades of life, whilst non-cyclical breast pain most often occurs in the fourth and fifth decades of life (Smith et al., 2004). Movement-induced breast pain is related to excessive movement of the breasts during exercise (Mason et al., 1999; Scurr et al., 2010) and therefore could be experienced by women of all ages.

9.1.2 Additional groups

As in the previous chapter, respondents with breast pain will be compared to respondents who were not experiencing breast pain, and then respondents with larger breasts (DD and above) will be compared to respondents with smaller breasts (D and below). As previously discussed within this thesis, breast pain can be improve by a well-fitting and supportive bra, and caused by a poorly fitting one, therefore women with breast pain are likely to have greater interest in the bra prescription service. Also, women with larger breasts have greater difficulty in finding well-fitting and supportive bras due to the size and shape of their breasts (Greenbaum et al., 2003), therefore it is likely they will have greater interest in this type of service.

Additionally, whether women are meeting physical activity guidelines will also be explored as breast pain has been frequently associated with excessive breast motion which is often caused by physical activity (Mason et al., 1999; Scurr et al., 2010). Sports bras are known to reduce this excessive breast motion (Mason et al., 1999; Scurr et al., 2010), therefore, an individual bra prescription focussing on sports bras for those who are physically active may be of benefit. Sports bras come in a variety of styles and impact levels (low, medium and high) for different activities so finding the correct sports bra can be difficult. Research has identified that difficulty in finding the correct sports bra and breast pain were barriers to physical activity in women (Burbage & Cameron, 2016; Burnett et al., 2015). There are also a large number of sports bra features that are disliked by women and this subsequently results in less sports bra use (Bowles et al., 2012). The most recent Department of Health Physical Activity guidelines (2011) currently state that 150 minutes of moderate or 75 minutes of vigorous activity per week are recommended alongside strength training at least two days per week (Physical activity guidelines for Adults (19-64 years), 2011) These guidelines can be used to categorise respondents into “meets guidelines” or “does not meet
guidelines" groups for comparison. Therefore, due to the likelihood of this group experiencing movement-induced breast pain and the difficulty in finding sports bras, it was important to investigate this group.

The sub-groups that will be explored within this study are:

- Women experiencing breast pain
- Women not experiencing breast pain
- D cup size and below
- DD cup size and above
- Meeting physical activity guidelines
- Not meeting physical activity guidelines

Distance from Portsmouth will be the final variable under consideration. Currently the bra prescription service runs with equipment and researchers based at the University of Portsmouth, so it is important to identify whether attending the University of Portsmouth is a barrier for respondents. This will identify if there is a need to further develop the service to one which can be run within the hospital setting, making it more accessible. Research suggests that for a service to be successful it must be accessible as well as flexible and frequent (Rudolf et al., 2006, cited in Craig et al., 2008). Therefore, whether interest decreases the further away from Portsmouth the respondent lives is a consideration when scoping for the level of interest in the bra prescription service.

### 9.1.3 Group allocation

Respondents were initially sorted into one of primary groups (Figure 9.1); pregnancy/breastfeeding, breast surgery, breast cancer, young adults (18 to 39 years), middle-aged adults (40 to 54 years) and older adults (55 years and above). All respondents (regardless of primary group allocation) were then grouped into (Figure 9.1); experiencing breast pain or not experiencing breast pain, women with larger breasts or women with smaller breasts. Respondents who were allocated to the primary ages groups (young adults, middle-aged adults or older adults) were also grouped into meeting physical activity guidelines or not meeting physical activity guidelines (Figure 9.1). All respondents will have their interest in the bra prescription service cross tabulated with their proximity to Portsmouth (distance, there will be no grouping).
Figure 9.1: Group assignment for all respondents who completed the questionnaire.
9.1.4 Survey development

The survey developed in Chapter Eight (section 8.2.3) was also used for this cohort. A few questions were amended to suit this study (Appendix L). The order of the questions was revised to ensure respondents would only complete relevant questions depending on the primary group they were allocated to. Firstly, filter questions were added to identify respondents who were pregnant or breastfeeding, have had breast surgery or were recovering from breast cancer. Additional questions were asked of respondents who identified in any of these primary groups. These questions related to the type of surgery they had, and whether they experienced breast pain prior to pregnancy, surgery or having breast cancer.

Questions to assess interest in finding a well-fitting and supportive bra and in the bra prescription service amongst the primary and additional groups within this study were revised. In the previous chapter respondents at the clinic were asked whether they were interested in the service (yes/no). This was revised a numerical rating scale response (0 to 10). An additional question was added which asked respondents whether they would take up the service (yes/no). Fisher and Clayton (2012) recommended using questions with dichotomous answers as they minimise any ambiguity and provides a definitive answer to a question. This change was made to differentiate between those respondents who were interested in the service and those who would actually take it up. This was to ensure it was clear who had an interest in the bra prescription service and would actively use this type of service if offered to them, rather than respondents who think the service is interesting, but not enough to take it up.

The three key questions of the survey asked; whether respondents had an interest in receiving help to find a well-fitting and supportive bra; whether they would have an interest in the bra prescription service (which would identify whether the bra prescription service meets the need for help to find a well-fitting and supportive bra); and whether respondents would take-up the bra prescription service.

An additional question was added to ask respondents to provide the first part of their postcode. The data collected from this question was analysed to investigate whether distance was an influencing factor on interest and take up of the service.

9.1.5 Aims

This study aimed to understand;

1. Whether respondents within each cohort (pregnancy/breastfeeding, breast cancer, breast surgery and age) would be interested in help to find a well-fitting and supportive bra.
2. Whether age, breast pain, bra size or distance correlates with interest in the bra prescription service aimed at reducing breast pain and improving quality of life.

3. Whether respondents within each cohort (pregnancy/breastfeeding, breast cancer, breast surgery and age) would take up the bra prescription service.

4. Whether respondents within the additional groups (breast pain, bra size and level of physical activity) would take up the bra prescription service.

5. The barriers to the uptake of this type of service within each cohort.

6. Whether respondents within each cohort think they wear well-fitting and supportive bras.

7. Whether respondents within the cohort experience any problems with their bras currently.

8. The advice respondents within the cohort would want from the bra prescription service.

### 9.1.6 Hypotheses

**H1:** Interest in finding a well-fitting and supportive bra will significantly differ between cohorts (pregnant/breastfeeding, breast cancer, breast surgery, young adults, middle aged adults and older adults).

**H2:** There will be a significant positive correlation between age and interest in the bra prescription service.

**H3:** There will be a significant difference in reported take up of the bra prescription service between cohorts; pregnant/breastfeeding, breast cancer, breast surgery, young adults, middle aged adults and older adults.

**H4:** There will be a significant positive correlation between breast pain intensity and interest in the bra prescription service.

**H5:** Women who have breast pain will report significantly greater take up of the bra prescription service compared to those who do not have breast pain.

**H6:** There will be a significant positive correlation between an increase in bra size and interest in the bra prescription service.

**H7:** Women with larger breasts will report a significantly greater take up of the bra prescription service compared to women with smaller breasts.

**H8:** Women who meet physical activity guidelines will report a significantly greater take up of the bra prescription service compared to those who do not meet physical activity guidelines.
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H₃: Interest in the bra prescription service will be significantly higher the closer to Portsmouth the respondent lives

9.2 Methods

9.2.1 Participants
Respondents were able to complete the survey if they were female, aged 18 years and over and lived in the UK. By completing the survey respondents gave informed consent to participate in this study.

9.2.2 Procedures
Respondents were recruited by advertising on the University of Portsmouth’s intranet pages. Previous participants for the Research Group in Breast Health who had expressed an interest in participating in future studies were also contacted. The majority of the recruitment was completed via convenience sampling with some snowball sampling involved as respondents were encouraged to pass the survey on to anyone who may want to complete the survey. The survey was also advertised by word of mouth. To ensure enough surveys were completed by the specific groups, specific groups/charities were contacted to complete the survey including; The Women’s Institute, The National Childbirth Trust and Breast Cancer Charities. Additional groups/charities were contacted if they appeared suitable.

Respondents could stop completing the survey at any time. Once the survey was completed however, as it was anonymous, respondents were not able to retract the data. Data were only removed by the researcher if it looked faked or unusable (for example, respondents defacing questions, or invalid answers).

9.2.3 Data analysis
All data were coded during data entry as per section 8.2.6 and split into the groups for investigation (Figure 8.1). All data were analysed descriptively and failed to meet parametric assumptions (Kolmogorov-Smirnov ≤ 0.05). Therefore, non-parametric statistical tests were completed on all data. A minimum of 50 respondents per group was needed for Chi-Squared analysis, where this was not achieved a Fisher’s Exact Test was completed. Respondents who did not fully complete the surveys were included in the analysis, the numbers of respondents who completed each question are presented in any findings.

9.2.3.1 Baseline measure
The proportion of respondents in each primary group with breast pain was statistically analysed using a binomial test with a 0.52 proportion based on 52% of the general population experiencing breast pain (Scurr et al., 2014). This showed whether the
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proportion of respondents in each primary group who experience breast pain significantly differed from the proportion in the UK general population.

9.2.3.2 Interest in receiving help to find a well-fitting and supportive bra (Yes/No)

Chi-square tests for proportions were used throughout the analysis to assess the proportions of respondents within and between primary and additional groups who were interested in finding a well-fitting and supportive bra. Mann-Whitney U tests with a Bonferroni correction ($P \leq 0.003$) were used for post hoc analyses to identify where significant differences occurred.

9.2.3.3 Interest in the bra prescription service (NRS 0 to 10 scale)

To assess the effect of breast pain, bra size and distance on interest in the bra prescription service, a Kendall’s Tau-b analysis ($P \leq 0.05$) was completed. This is a non-parametric test of association, where +1/-1 = perfect association and 0 = no association (Liu et al., 2016). A very strong correlation is reported to be >0.70, a strong correlation is >0.50 to ≤0.70, a weak correlation is >0.20 to ≤0.50 and a non-important correlation is >0.00 to ≤0.20 (Kozak, 2009).

9.2.3.4 Whether they would take up the bra prescription service (Yes/No)

Chi-square tests for proportions were used throughout the analysis to assess the proportions of respondents within and between primary and additional groups who would take up the bra prescription service. Mann-Whitney U tests with a Bonferroni correction ($P \leq 0.003$) were used for post hoc analyses to identify where significant differences occurred. The respondent’s postal codes were used to assess interest in the service relating to proximity to the University of Portsmouth, where the service would initially be held. These data allow for the assessment of whether the location of the service limits whether a participant would take up the service. Data were grouped into 50 mile radiuses. A Fishers exact test for proportions (as there were fewer than 5 people in some groups) was completed ($P \leq 0.05$). A Mann-Whitney U test was completed for post hoc comparisons with a Bonferroni correction ($P \leq 0.0009$).

9.3 Results

9.3.1 Participants

There were 962 responses for the survey. Of this, 42 surveys were removed due to being unusable, leaving a final useable sample size of 920 surveys across the six primary groups (Table 9.1). The average age of the respondents was 51 years (SD = 17) (Table 9.1).
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Table 9.1: Number of respondents and average ages of the respondents in each cohort

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Total number of responses (n)</th>
<th>Age ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy and Breastfeeding</td>
<td>66</td>
<td>32 ± 4 years</td>
</tr>
<tr>
<td>Breast Surgery</td>
<td>59</td>
<td>59 ± 14 years</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>87</td>
<td>61 ± 12 years</td>
</tr>
<tr>
<td>Young adult (18 to 39 years)</td>
<td>196</td>
<td>29 ± 6 years</td>
</tr>
<tr>
<td>Middle-aged adult (40 to 54 years)</td>
<td>160</td>
<td>48 ± 5 years</td>
</tr>
<tr>
<td>Older adult (55 years and above)</td>
<td>352</td>
<td>66 ± 7 years</td>
</tr>
</tbody>
</table>

Three hundred and thirty eight (37%) respondents experienced breast pain. Breast pain was least common in older adults with less than a third experiencing breast pain. Breast pain was experienced by almost half of respondents within the breast cancer group. A binomial test was completed to assess whether each of the primary groups in Table 9.2 had significantly different percentages of women who experience breast pain compared to the 52% of women reported in the literature (Scurr et al., 2014). Young adults, middle-aged adults, older adults and the pregnancy and breastfeeding group were experiencing significantly lower levels of breast pain that the average UK woman.

Table 9.2: Number of respondents within each cohort who experience breast pain and modal intensity (out of 10). * denotes a significant difference for the binomial test ($P$ ≤0.05).

<table>
<thead>
<tr>
<th>Cohort</th>
<th>N</th>
<th>%</th>
<th>Modal intensity</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young adults</td>
<td>82</td>
<td>42</td>
<td>3</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Middle-aged adults</td>
<td>66</td>
<td>41</td>
<td>2</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Older adults</td>
<td>100</td>
<td>28</td>
<td>3</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Pregnancy and breastfeeding</td>
<td>25</td>
<td>38</td>
<td>3</td>
<td>0.02*</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>42</td>
<td>48</td>
<td>4</td>
<td>0.32</td>
</tr>
<tr>
<td>Breast surgery</td>
<td>27</td>
<td>46</td>
<td>3</td>
<td>0.20</td>
</tr>
<tr>
<td>Total/Total/Mode</td>
<td>338</td>
<td>41</td>
<td>3</td>
<td>-</td>
</tr>
</tbody>
</table>

Twenty-four percent of respondents in the pregnancy and breastfeeding group reported experiencing breast pain prior to their pregnancy (Table 9.3). Only 13% of respondents in the breast cancer group reported experiencing breast pain prior to their breast cancer diagnosis (Table 9.3).
Table 9.3: Past experiences of breast pain in the pregnancy and breastfeeding and the breast cancer group.

<table>
<thead>
<tr>
<th>Cohort</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pregnancy and breastfeeding</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experienced breast pain prior to pregnancy</td>
<td>66</td>
<td>100</td>
</tr>
<tr>
<td>Pregnant</td>
<td>16</td>
<td>24</td>
</tr>
<tr>
<td>Pregnant and experiencing breast pain</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>Attributing breast pain to pregnancy</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Breast feeding</td>
<td>50</td>
<td>76</td>
</tr>
<tr>
<td>Breastfeeding and experiencing breast pain</td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>Breastfeeding and experienced breast pain during pregnancy</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Attributing breast pain to breastfeeding</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td><strong>Breast cancer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experienced breast pain prior to being diagnosed with breast cancer</td>
<td>87</td>
<td>100</td>
</tr>
</tbody>
</table>

Respondents in each primary group reported whether they currently wore a bra. Across all groups between 97% and 99% of respondents were wearing a bra. Modal bra sizes were similar across primary groups, with an under band of 34 and a cup size of a D being most common (Table 9.4).

Table 9.4: Modal under band and cup sizes for the six primary groups of respondents

<table>
<thead>
<tr>
<th>Cohort</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pregnancy and breastfeeding</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experienced breast pain prior to pregnancy</td>
<td>66</td>
<td>100</td>
</tr>
<tr>
<td>Pregnant</td>
<td>16</td>
<td>24</td>
</tr>
<tr>
<td>Pregnant and experiencing breast pain</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>Attributing breast pain to pregnancy</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Breast feeding</td>
<td>50</td>
<td>76</td>
</tr>
<tr>
<td>Breastfeeding and experiencing breast pain</td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>Breastfeeding and experienced breast pain during pregnancy</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Attributing breast pain to breastfeeding</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td><strong>Breast cancer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experienced breast pain prior to being diagnosed with breast cancer</td>
<td>87</td>
<td>100</td>
</tr>
</tbody>
</table>

Seven hundred and seventy respondents (80%) reported their physical activity levels. Of these, 57% (n = 440) met physical activity guidelines and 43% (n = 270) did not meet physical activity guidelines.
9.3.2 Outcomes

9.3.2.1 Cohorts

The pregnancy and breastfeeding group had the greatest interest in finding a well-fitting and supportive bra (Figure 9.2). However, there was no significant difference between interest in finding a well-fitting and supportive bra between all of the cohorts ($\chi^2 = 8.288, p = 0.141$, Cramer’s V = 0.096).

Interest in the bra prescription service was significantly different between the groups ($\chi^2 = 13.194, P = 0.018$), and post hoc tests identified that the young adults group had significantly more interest in a bra prescription service than the older adults group ($U = 27915.500, P < 0.001, r = 0.14$). There were no other significant differences between the groups. There was a significant, but irrelevant, negative association ($r_b = -0.099, P < 0.001$) between age and interest in the bra prescription service showing that as age increased interest decreased.

The pregnancy and breastfeeding group had the highest number (82%) of respondents reporting they would take up the service (Figure 9.2). Significant differences were reported in the take up of the service between the groups ($\chi^2 = 43.679 P < 0.001$). The pregnancy or breastfeeding group were significantly more likely to take up the service than the breast surgery group ($U = 1099.000, P < 0.001, r = -0.43$), the breast cancer group ($U = 2060.000, P = 0.002, r = -0.27$), the middle-aged adults ($U = 4016.000, P < 0.001, r = -0.21$) and the older adults ($U = 7888.500, P < 0.001, r = -0.22$). The young adults group were more likely to take up the service than the breast surgery group ($U = 3877.000, P < 0.001, r = -0.28$) and the older adults group ($U = 27135.500, P < 0.001, r = 0.19$).
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Figure 9.2: Interest in finding a well-fitting and supportive bra and reported take up of the bra prescription service within the six cohorts.

The relationship between breast pain and each of the six cohorts was investigated. Significantly more respondents who were experiencing breast pain reported that they would take up the service compared to those not experiencing breast pain in the breast cancer group (breast pain = 56%, no breast pain = 29%, $\chi^2 = 5.074$, $P = 0.024$, Cramer’s $V = 0.264$) and the older adults group (breast pain = 64%, no breast pain = 49%, $\chi^2 = 6.946$, $P = 0.009$, Cramer’s $V = 0.142$).

9.3.2.2 Sub-groups

9.3.2.2.1 Breast pain

There was a significant but non-important association between interest in the service and breast pain intensity ($\tau_b = 0.127$, $P = 0.002$), with interest increasing as breast pain intensity increased.

Breast pain was also a significant indicator of take up of the bra prescription service ($\chi^2 = 20.186$, $P < 0.001$, Cramer’s $V = 0.150$), 72% of those with breast pain reported they would take up the service compared to 55% without breast pain.

9.3.2.2.2 Bra size
Comparing interest in the bra prescription service in non-clinical cohorts

There was a significant but non-important association between interest in the service and bra cup size \( (\tau_b = 0.067, P = 0.008) \), with an interest increasing as bra size increased.

Bra cup size significantly related to whether the service would be taken up (D and below = 57%, DD and above = 65%, \( \chi^2 = 6.353, P = 0.013 \), Cramer’s V = 0.085) with women with larger cup sizes more likely to take up the service.

9.3.2.2.3 Physical activity level

Meeting physical activity guidelines significantly related to take up of the bra prescription service \( (\chi^2 = 13.335, P = <0.001) \). Sixty-five percent of respondents who met guidelines would take the service up compared to 52% of respondents who did not meet guidelines.

9.3.2.3 Distance

A significant strong negative association was identified between distance and interest in the bra prescription service \( (\tau_b = -0.92, P = <0.001) \). This showed that as distance increased, interest decreased significantly.

There was a significant difference between distance from Portsmouth and the reported take up of the service \( (\chi^2 = 155.423, P = <0.001, \text{Table 9.5}) \). Respondents who lived <50 miles away were more likely to take up the service compared to those who lived; 100.0 and 149.9 miles away \( (U = 17733.000, P = <0.001, r = -0.22) \), 150.0 to 199.9 miles away \( (U = 8127.500, P = <0.001, r = -0.20) \) and 200.0 to 249.9 miles away \( (U = 7353.500, P = <0.001, r = -0.31) \). Fewer significant results were seen than expected as the small sample of respondents who lived 300.0 to 349.9 miles and above from Portsmouth skew the proportions.
**Table 9.5: Number of respondents who would take up the bra prescription service by distance from Portsmouth**

<table>
<thead>
<tr>
<th>Distance (miles)</th>
<th>Take up</th>
<th>Proportion of take up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>&lt; 50</td>
<td>202</td>
<td>67</td>
</tr>
<tr>
<td>50 to 99.9</td>
<td>125</td>
<td>83</td>
</tr>
<tr>
<td>100 to 149.9</td>
<td>90</td>
<td>78</td>
</tr>
<tr>
<td>150 to 199.9</td>
<td>41</td>
<td>37</td>
</tr>
<tr>
<td>200 to 249.9</td>
<td>34</td>
<td>49</td>
</tr>
<tr>
<td>250 to 299.9</td>
<td>22</td>
<td>18</td>
</tr>
<tr>
<td>300 to 349.9</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>350 to 399.9</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>400 to 449.9</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>450 to 499.9</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>&gt; 500</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

**9.3.3 Barriers to using the service**

The most reported barrier for the pregnant and breastfeeding group and the young adults group was “I would find it difficult to find time to attend this service” (Figure 9.3). For the remaining primary groups the most frequently reported barrier was “I would not want to attend the University of Portsmouth for this service.”
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Figure 9.3: Barriers to taking part in the bra prescription service.
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Respondents were also requested to provide any other barriers to attending the service in addition to those provided in the list (Table 9.6). The most reported other reason was a combination of distance, travel and the cost of attending the service and this was reported by 224 participants.

**Table 9.6: Additional reasons provided by respondents as barriers for attending the service**

<table>
<thead>
<tr>
<th>Reason</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance, travel and associated costs</td>
<td>224</td>
</tr>
<tr>
<td>Bra fitting services used elsewhere</td>
<td>48</td>
</tr>
<tr>
<td>Time and effort</td>
<td>13</td>
</tr>
<tr>
<td>Embarrassment, anxiety or shyness</td>
<td>11</td>
</tr>
<tr>
<td>Participants are unable to find bras/feel like they are beyond help</td>
<td>8</td>
</tr>
<tr>
<td>Health reasons</td>
<td>7</td>
</tr>
<tr>
<td>Cost of service</td>
<td>5</td>
</tr>
<tr>
<td>Childcare</td>
<td>4</td>
</tr>
<tr>
<td>Poor services used before</td>
<td>3</td>
</tr>
<tr>
<td>Age</td>
<td>3</td>
</tr>
<tr>
<td>Bra styles available</td>
<td>2</td>
</tr>
<tr>
<td>Scepticism about the service</td>
<td>2</td>
</tr>
<tr>
<td>Would want custom made designs not on the high street</td>
<td>2</td>
</tr>
<tr>
<td>How trained the fitter was</td>
<td>2</td>
</tr>
<tr>
<td>Confidentiality reasons</td>
<td>1</td>
</tr>
<tr>
<td>Ability to purchase bras after the service</td>
<td>1</td>
</tr>
<tr>
<td>Recovering from surgery</td>
<td>1</td>
</tr>
<tr>
<td>Cost of bras</td>
<td>1</td>
</tr>
<tr>
<td>Suitability of service for larger bra sizes</td>
<td>1</td>
</tr>
<tr>
<td>Availability of bras</td>
<td>1</td>
</tr>
<tr>
<td>Independence of service</td>
<td>1</td>
</tr>
<tr>
<td>Gender of researcher</td>
<td>1</td>
</tr>
<tr>
<td>Long winded way of finding a bra</td>
<td>1</td>
</tr>
<tr>
<td>Would want assurances that I am being measured correctly</td>
<td>1</td>
</tr>
<tr>
<td>Want to attend a shop</td>
<td>1</td>
</tr>
<tr>
<td>Required frequency to attend the service</td>
<td>1</td>
</tr>
<tr>
<td>Recently purchased bras</td>
<td>1</td>
</tr>
<tr>
<td>Lack of bra options</td>
<td>1</td>
</tr>
<tr>
<td>Availability of service outside of work hours</td>
<td>1</td>
</tr>
<tr>
<td>Unsure the service would provide what is needed</td>
<td>1</td>
</tr>
<tr>
<td>Don't understand the service</td>
<td>1</td>
</tr>
</tbody>
</table>
Comparing interest in the bra prescription service in non-clinical cohorts

9.3.4 Bras

Respondents in the primary groups were asked to report whether they currently experienced problems with their bras (Table 9.7). Despite respondents reporting that they were wearing a well-fitting bra, some still experienced problems with their bras (17% to 63%), although fewer than the respondents who reported wearing poorly-fitting bras (80% to 93%).

Table 9.7: The number and percentage of respondents (n (%)) within each primary group who reported to wear a well-fitting bra and who reported problems with their bras.

<table>
<thead>
<tr>
<th>Primary Group</th>
<th>Reported wearing a well-fitting bra n (%)</th>
<th>Reported problems with their bras n (%)</th>
<th>Reported wearing a poorly-fitting bra n (%)</th>
<th>Reporting problems with their bras n (%)</th>
<th>Missing responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy and Breastfeeding</td>
<td>36 (55%)</td>
<td>6 (17%)</td>
<td>28 (42%)</td>
<td>25 (86%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Breast Surgery</td>
<td>45 (76%)</td>
<td>27 (60%)</td>
<td>14 (24%)</td>
<td>13 (93%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>72 (83%)</td>
<td>45 (63%)</td>
<td>14 (16%)</td>
<td>12 (86%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Young adult</td>
<td>128 (65%)</td>
<td>35 (27%)</td>
<td>64 (33%)</td>
<td>51 (80%)</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Middle aged adult</td>
<td>122 (76%)</td>
<td>56 (46%)</td>
<td>35 (22%)</td>
<td>30 (86%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Older adult</td>
<td>273 (77%)</td>
<td>130 (48%)</td>
<td>75 (21%)</td>
<td>67 (80%)</td>
<td>5 (1%)</td>
</tr>
</tbody>
</table>

The most common bra problem experienced by respondents was related to the bra straps (Figure 9.4). This was followed by general bra fit problems and the bras rubbing, pinching, chafing and digging into the skin.
Comparing interest in the bra prescription service in non-clinical cohorts

Figure 9.4: Bra problems (n) experienced by the respondents, across the primary groups in this study.

<table>
<thead>
<tr>
<th>Poor fit (393)</th>
<th>Comfort (83)</th>
<th>Purchasing factors (88)</th>
<th>Support (52)</th>
<th>Anatomical issues (51)</th>
<th>Practicalities (42)</th>
<th>Aesthetics (23)</th>
<th>Fabric (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strap problems (including falling off or not sitting right on shoulders) (103)</td>
<td>Lack of comfort (83)</td>
<td>Size is not widely available (27)</td>
<td>Lack of support (48)</td>
<td>Breasts are asymmetrical (21)</td>
<td>Bra size varies within and between brands (25)</td>
<td>Bras are unattractive (8)</td>
<td>Allergies or rubbing from fabric (7)</td>
</tr>
<tr>
<td>Bras are poorly fitting (80)</td>
<td>Lack of choice (26)</td>
<td>Lack of choice (26)</td>
<td>Bras do not provide enough lift (3)</td>
<td>Bras irritate scars, skin or medical devices (e.g. pacemakers) (21)</td>
<td>Bras are old or broken (14)</td>
<td>Bras are a poor shape (7)</td>
<td>Fabric elasticity (too much or too little) (2)</td>
</tr>
<tr>
<td>Bras rub, pinch, chafe or dig into skin (80)</td>
<td>Difficult to find secure post-surgery bras which keep prosthesis secure (5)</td>
<td>Good fitting bras have been discontinued (4)</td>
<td>Difficulty finding bras now older (8)</td>
<td>Bra size changes (menstrual cycle, pregnancy, breastfeeding) (7)</td>
<td>Bras need replacing often (7)</td>
<td>Difficult to wear bras under clothes (5)</td>
<td>Bras are hand wash only (2)</td>
</tr>
<tr>
<td>Bras are restrictive on chest (35)</td>
<td>Difficulty finding nursing bras (2)</td>
<td>Difficult to find post-surgery bra (3)</td>
<td>Bras are poor quality (1)</td>
<td>Lack of shoulder flexibility to adjust bras properly (2)</td>
<td>Would prefer post-surgery bras to only have a pocket on one side (1)</td>
<td>Bras do not cover modesty (2)</td>
<td>Bras hold moisture after physical activity (1)</td>
</tr>
</tbody>
</table>
9.3.5 Advice wanted from the service

Across all primary groups respondents wanted more advice on bra fitting (Figure 9.5). The young adults group reported wanting advice on sports bras more than all of the other groups.

**Figure 9.5**: Advice wanted within the bra prescription service by each group of respondents who completed the survey.

Respondents also reported any additional advice they would like to receive from the bra prescriptions service that was not already listed (Table 9.8). There were a small number of responses (n = 72) to this question but the most reported advice wanted was breast health advice, which included advice on cancer, breast pain, cancer signs and the effect of medication on the breasts.
Comparing interest in the bra prescription service in non-clinical cohorts

Table 9.8: Advice wanted by respondents within the study

<table>
<thead>
<tr>
<th>Advice wanted</th>
<th>Number of responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Health (cancer/mastitis/effect of medication)</td>
<td>12</td>
</tr>
<tr>
<td>Specific bra style advice (e.g. nursing/sports)</td>
<td>10</td>
</tr>
<tr>
<td>Pregnancy/Nursing advice (bras and breast care)</td>
<td>7</td>
</tr>
<tr>
<td>Size specific advice</td>
<td>7</td>
</tr>
<tr>
<td>Where to find supportive bras</td>
<td>5</td>
</tr>
<tr>
<td>Where to find comfortable bras</td>
<td>4</td>
</tr>
<tr>
<td>What bras are kind to skin</td>
<td>4</td>
</tr>
<tr>
<td>Bra care</td>
<td>3</td>
</tr>
<tr>
<td>Any advice (full breast education)</td>
<td>2</td>
</tr>
<tr>
<td>How to find affordable cheap bras that fit</td>
<td>2</td>
</tr>
<tr>
<td>Posture, breasts and bras</td>
<td>2</td>
</tr>
<tr>
<td>Advice on under wires</td>
<td>2</td>
</tr>
<tr>
<td>Advice on shape and appearance</td>
<td>2</td>
</tr>
<tr>
<td>How to stop back pain and skin problems</td>
<td>2</td>
</tr>
<tr>
<td>Breast sag</td>
<td>1</td>
</tr>
<tr>
<td>How to prevent skin problems relating to sweating during sport</td>
<td>1</td>
</tr>
<tr>
<td>Where to buy good bras</td>
<td>1</td>
</tr>
<tr>
<td>Whether you should wear a bra to bed</td>
<td>1</td>
</tr>
<tr>
<td>How to stop straps slipping</td>
<td>1</td>
</tr>
<tr>
<td>Why bras are expensive and badly fitting bras are marketed and sold</td>
<td>1</td>
</tr>
<tr>
<td>Swimwear post-surgery</td>
<td>1</td>
</tr>
<tr>
<td>Fabric advice</td>
<td>1</td>
</tr>
</tbody>
</table>

9.4 Discussion

This aim of this chapter was to assess the interest in the bra prescription service with alternative cohorts to ensure the bra prescription service is directed to the most appropriate cohorts and to compare this with the clinical cohort.

9.4.1 Cohorts

This study aimed to understand whether respondents would be interested in finding a well-fitting and supportive bra. Interest in finding a well-fitting and supportive bra was high across all groups and not significantly different between the primary groups (range = 71% to 82%), rejecting hypothesis one. The percentages of interest in finding a well-fitting and supportive
Comparing interest in the bra prescription service in non-clinical cohorts

bra within the non-clinical cohorts (71% to 82%) was higher than the clinic sample from Chapter Eight (44%). It is possible that the clinic sample were less interested in this help as they were worried about a particular breast problem. The clinical cohort also reported a higher percentage were wearing well-fitting and supportive bras (83.5%), compared to a range of 55% to 77% for the cohorts in this study, except for the breast cancer group where 83% reported that they felt they were wearing a well-fitting and supportive bra. It is possible that the respondents within the clinic study (Chapter Eight) were pre-occupied with the problem for which they were attending the clinic. Consequently, this may have distracted them from fully considering the bra prescription service. Additionally, the clinic patients may have just wanted reassurance their pain was not breast cancer.

This study also aimed to identify whether age correlated with interest in the bra prescription service. Hypothesis two was accepted as age significantly correlated with interest in the bra prescription service. This showed that as age increased, interest decreased. The reasons for this could be explained by the differences between the barriers to participating in the bra prescription service across the age groups, which are detailed further below.

Respondents who were pregnant or breastfeeding were significantly more likely to take up the service (82%) than respondents within the breast surgery (41%), breast cancer (56%), middle-aged adults (61%) and older adults groups (52%). The young adults group were significantly more likely to take up the service (72%) over the breast surgery and older adults groups, accepting hypothesis three. Although not entirely comparable due to the question changes described in section 8.2.2, the reported take up of the service was higher for all groups compared to the clinic sample (43%) except for the breast surgery group. The results of this study identified that the pregnancy/breastfeeding and young adults are the groups most likely to take up a bra prescription service. It is surprising that the pregnant and breastfeeding group were the group most likely to take up the service as only 17% reported problems with the bras they wear. The reason for this could be due to an awareness of the breast changes during pregnancy and after pregnancy, particularly the engorgement during pregnancy and the fluctuations in size during breastfeeding (Hassiotou & Geddes, 2013; Smith, 2016). Also it has been found that breastfeeding women struggle to find supportive sports and nursing bras that can reduce their breast pain (Morris et al., 2017). Additionally, these women are recommended to be fitted regularly during their pregnancy (Mothercare, n.d.).
9.4.2 Additional groups

9.4.2.1 Breast pain

This study also aimed to identify whether breast pain correlated with interest in the bra prescription service. For those participants with breast pain, as intensity of pain increased interest in the service also increased ($\tau_b = 0.127$, $P = 0.002$), showing that the more painful their breasts, the more likely they would partake in the service, accepting hypothesis four. This also further reiterates the choice of focusing the bra intervention on women who are experiencing breast pain in the previous chapters of this thesis. The prevalence of breast pain in the UK is high (52%) (Scurr et al., 2014) therefore, the bra prescription service has the potential to help a large number of women.

The clinic sample (Chapter Eight) identified that breast pain was not significantly related to interest ($\chi^2 = 3.074$, $P = 0.085$) in the bra prescription service despite more participants (than in this study) reporting breast pain and the modal intensity being comparable to the respondents in this study. This could suggest that the clinic sample was less appropriate for focusing the recruitment for the RCT (Chapter Six), and perhaps this can be attributed to the potential greater awareness of breast and bra issues. As a whole group breast pain was experienced by 37% of the respondents in this study, which is lower than the clinic sample (62%) and lower than the reported value for the general population in the UK (52%) (Scurr et al., 2014). The binomial tests found that all groups except the breast surgery and breast cancer groups had significantly lower incidence of breast pain than the 52% value reported in Scurr et al. (2014). But despite this, breast pain was a significant indicator of take up of the bra prescription service (72% interest for respondents with breast pain compared with 55% interest for respondents without breast pain) accepting hypothesis five. This result confirms the necessity of the service for non-clinical groups and confirms the appropriateness of targeting women suffering from breast pain.

9.4.2.2 Bra size

This study also aimed to identify whether bra size correlated with interest in the bra prescription service. As cup size increased so did the interest in the service ($\tau_b = 0.067$, $P = 0.008$), accepting hypothesis six. Breast size however, was not a significant indicator of interest in the clinic sample (Chapter Eight). This demonstrates the appropriateness of focusing the bra intervention on women with larger breasts over those with smaller breasts in this thesis, as they have a greater interest in this type of help with their bras. Therefore, alongside the results of the breast pain analysis, the results of this chapter demonstrate that both the breast pain and size criteria were appropriate for this thesis. Perhaps this then
suggests that recruiting patients from clinic was the less appropriate than recruiting from a non-clinical group, therefore suggesting that the non-clinical groups should be focussed on. Within this study, the split between larger (48%) and smaller (52%) cup sizes was negligible. A higher proportion of the DD and above group reported they would take up the service compared to the D and below group, accepting hypothesis seven. It suggests that choosing larger breasted women for the intervention (Chapter Six) was an appropriate choice.

9.4.2.3 Physical activity level

Hypothesis eight was accepted as more respondents who met physical activity guidelines would take up the bra prescription service over respondents who did not meet physical activity guidelines. Therefore, this group may need a specific service to prescribe sports bras for physical activity, although this was not specifically presented to the respondents as an option. Research has previously identified that reducing breast movement using a sports bra can reduce exercise induced breast pain (Mason et al., 1999; Scurr et al., 2010). Sports bras have also been used in a clinical setting for treating breast pain (Hadi, 2000) although it is important to note that sports bras may not be an appropriate solution for women to wear on a daily basis. Chapter Two of this thesis identified that women with larger breasts and breast pain did not want to wear a sports bra on a daily basis.

For those women who are not meeting physical activity guidelines, it is not surprising that their interest in the bra prescription service was lower. Previous research identified that the breast was a barrier to physical activity participation for almost a fifth of UK women (Burnett et al., 2015) and these barriers included being embarrassed by excessive breast movement and breast pain. It is therefore possible that these women are experiencing greater levels of self-consciousness and therefore would not partake in this type of service. Burnett et al. (2015) concluded that these issues can mostly be resolved by wearing a well-fitting and supportive sports bra. Therefore, promoting the benefits of a sports bra and conducting bra prescription for sports bras, may help women who are not meeting physical activity guidelines to do more physical activity.

9.4.3 Distance

This study also aimed to identify whether distance correlated with interest in the bra prescription service. Distance from Portsmouth had a strong negative correlation with interest in the service demonstrating that as distance from Portsmouth increased, interest in the bra prescription service decreased. This accepts hypothesis nine. This result identifies the need for an accessible service. Portsmouth, although easily accessible across the South Coast and from London, is at the bottom of the United Kingdom and therefore could easily be seen as a difficult location for many women to get to, consequently making
the bra intervention based in Portsmouth inappropriate to roll out across the NHS in the UK. Additional work would need to be completed to further develop the intervention into something that could be conducted more widely allowing for greater accessibility. This could mean redesigning the intervention into an accessible service that could be conducted within a hospital setting.

9.4.4 What are the barriers to taking up this type of service?
The location of the service was the main barrier for most groups, except for the young adults, and pregnancy and breastfeeding (which has a young average age) groups. This links with the correlation analysis which showed that interest in finding a well-fitting bra and the service decreased with age. Physical activity and functional fitness levels decrease with age (Milanovic et al., 2013) which suggests that older adults may be less able to travel longer distances for a service. This perhaps indicates the importance of developing a service that is more accessible and could be rolled out within NHS hospitals. Additionally, it is unsurprising that the top barrier for the young adults and the pregnancy and breastfeeding groups was time (“I would find it difficult to find time to attend this service”). Respondents in these groups are most likely to be in employment (62% of 18 to 24 year olds, 77% of 25 to 34 year olds, 79% of 35 to 49 year olds compared to 67% of 50 to 64 year olds and 7% of those age 65+; August to October 2017; (Office for National Statistics, 2017a)) or likely to be in full-time education (35% of 18 to 24 year olds; August to October 2017; (Office for National Statistics, 2017b)) and as average age of mothers in 2016 was 30.4 years (Office for National Statistics, 2017c), younger women are more likely to be pregnant or have young children living at home. This would restrict the time available for these respondents to take up this type of bra prescription service.

9.4.5 Do respondents think they wear well-fitting and supportive bras?
The smaller proportion (range = 55% to 77%) of women in this study compared to the clinic study (Chapter Eight, except for the breast cancer group who equalled the clinic group = 83%) that report they are wearing well-fitting bras may indicate a need to improve bra fit knowledge within these groups. Previous research recommends educating women on bra fit via medical practitioners during consultations (McGhee & Steele, 2010b), the bra prescription service can aid in facilitating this recommendation with the addition of bra fit educational material within the scope of the intervention. Previous research (conducted on adolescent female athletes) has identified that bra fit improves with breast education (McGhee et al., 2010) supporting the use of educational material. This type of material could be developed for women within a clinic and non-clinic environment to supplement the bra
Comparing interest in the bra prescription service in non-clinical cohorts

prescription service or as a precursor to ensure patients/public are aware of the importance of good bra fit.

There was an additional barrier to the bra prescription service reported by respondents in the breast cancer cohort. This barrier was that 83% reported wearing a well-fitting and supportive bra. This would be a limitation to applying the bra prescription service to this group as they may feel they do not need new bras. As this group will be currently or have historically received treatment and most likely a large volume of breast health/care advice, bra fit advice may already have been part of this treatment.

9.4.6 Do respondents experience any problems with their bras currently?
Respondents in the clinic sample (Chapter Eight) identified fewer problems with their bras (20%) than the groups within this study (range = 27% to 63%) except for the pregnancy and breastfeeding group (17%). It is possible that the pregnancy and breastfeeding group have had a more recent bra fitting than the other groups. Previous research has identified that bra straps of a sports bra can dig and cut into the skin (Bowles et al., 2012). This chapter of the thesis has identified that this is a similar problem for women in everyday bras as bra straps were most the commonly reported bra problem (section 8.3.5). Bra strap furrows are commonplace for women with larger breasts, and are as a result of the narrow bra straps digging in because of high levels of pressure on the shoulders (Bowles & Steele, 2013). The bras chosen for the bra intervention all used the vertical strap orientation only, and this configuration has anecdotally been reported to be most effective at reducing vertical breast motion (Coltman, McGhee, & Steele, 2016). This means that the bras chosen within Chapter Three for the bra intervention are likely to provide more support, than other bras on the market with different strap orientations. Other strap orientations such as racer back designs help to minimise the slippage of the bra straps (Coltman et al., 2016), so perhaps bras need to be designed so that they have multiway straps and the wearer can choose the configuration that is most appropriate for them.

9.4.7 What advice do respondents want from this service?
All groups wanted advice on bra fitting. Educating women on bra fit can result in improvements in the fit of their bras (McGhee et al., 2010). The traditional method of bra fitting is known to be inaccurate therefore any bra fitting advice, should encourage the five-point best fit method (White & Scurr, 2012). Physical activity levels for women are at their highest in their younger years and reach a peak at ages 25 to 34 years (Townsend et al., 2012). Therefore, it is unsurprising that there was a large number of women in the young adults group who also wanted advice on sport bras (Figure 9.5). It is also possible that younger women are more likely to experience exercise induced breast pain due to
completing the most physical activity. The purpose of a sports bra is different to that of an everyday bra, as the sports bras main purpose is to reduce the excessive movement of the breasts during exercise. Exercise induced breast pain can be reduced by a sports bra (McGhee & Steele, 2010b; Scurr et al., 2010). Therefore, it may be appropriate to identify the sports bra needs of these women and develop the bra intervention to focus on prescribing sports bras. Parts of the intervention (for example the weightings) may require altering to suit the purpose of the bra. The comfort and support of a sports bra is highly correlated, an increase in comfort occurs with an increase in support (Lawson & Lorentzen, 1990). To prescribe a sports bra, it could be suggested that support should be weighted highest as this would have a positive influence on comfort.

Respondents across all groups wanted advice on what bra styles to wear and which styles that they should not wear. This is important as this can be tailored for each of the primary groups, for example, for the pregnancy and breastfeeding group it is important that this advice focusses on maternity and nursing bras. These styles are typically non-wired, as this design minimise any potential for wires digging into the skin, which is more likely as the breasts are changing size and can obstruct milk-ducts (Morris et al., 2017; “When to buy Nursing and Maternity bras guide,” 2018). Breast Cancer Care currently provide guidance as to the style that should be worn by women recovering from breast cancer, including wearing non-wired bras and considering bras with pockets for breast prostheses (“Bras after surgery for breast cancer,” 2018). As the guidance provided by Breast Cancer Care is detailed, this may also be why respondents within the breast cancer group felt they were wearing a well-fitting and supportive bra.

9.5 Conclusion

To conclude, this study identified that the group with the greatest interest in wearing a well-fitting and supportive bra and the greatest likelihood to take up the bra prescription service was the pregnancy and breastfeeding group, possibly due to the acute breast changes they are currently undergoing. Meeting physical activity guidelines also was a significant indicator of interest in the bra prescriptions service showing that the remit of the service could also be expanded to include sports bra prescriptions along with specialist bras, for example maternity and nursing. Having breast pain and larger breasts meant respondents were significantly more likely to take up the service confirming some of the inclusion criteria in Chapter Six.

Fewer respondents in each of the groups (except the breast cancer group) reported wearing a well-fitting and supportive bra than the clinic group (Chapter Eight), again providing an indication why the clinic group may have had less interest in a bra prescription service.
Comparing interest in the bra prescription service in non-clinical cohorts

Despite their greater likelihood to take up the service, the pregnancy and breastfeeding group reported fewer problems with their bras. It could be that these women are more health and wellbeing-aware and as a consequence they may be more breast-aware. The breast surgery group reported the most problems with their bras, but they were the least likely to take up the bra prescription service. (Reardon & Grogan, 2011) investigated reasons why women seek breast reductions found that bras were a problem for women in the study as they; experienced deep shoulder grooving from the bras due to the weight of their breasts, found it difficult to find appropriate bras and found bras for women with larger breasts expensive. So for women who seek breast reduction surgery, it would be expected that they would welcome assistance in the form of a bra. Perhaps other types of surgery, such as cyst removal, does not necessarily make changes to the size or shape of the breasts, therefore perhaps this type of surgery does not have an effect on the bra being worn.

Time was the greatest barrier to the bra prescription service for the pregnancy/breastfeeding and young adults’ cohort’s. This is perhaps due to work and child commitments, which has to be considered when further developing the bra intervention if applied to the general population. For the other groups, the location of the bra prescription service (University of Portsmouth) was the key barrier. This may indicate that the bra prescription service would need to be more mobile for it to be taken up by more women. Additionally, advice on sports bras was the second highest reported advice wanted by the young adults group and should be incorporated into the intervention.

To conclude, this study and Chapter Eight have identified that the bra intervention is warranted, but those patients within the clinical population need further education to ensure they understand the benefits of appropriately fitting bras. The next chapter (general discussion) will bring together the chapters of this thesis to provide an overview of the development, piloting and evaluation phases of the bra intervention. It will also evaluate where the intervention could be adapted to improve effectiveness in line with the Medical Research Council guidelines (Craig, Dieppe, Macintyre, Mitchie, et al., 2008).
10  Chapter Ten: General Discussion

10.1  Summary of the key findings (Table 10.1)

Table 10.1: A summary of the key findings

\textbf{Development Phase}

\textbf{Chapter One}

- Breast pain is a highly prevalent condition which negatively affects QoL.
- Bras are widely recommended as a treatment for breast pain.
- Bras have been effective at reducing breast pain but no randomised controlled trial has been conducted to confirm these findings.
- Therefore this thesis aimed to develop, pilot and evaluate a bra intervention for women with larger breasts who are experiencing breast pain, with the aim of improving breast pain and QoL.

\textbf{Chapter Two}

- The four KPI’s determined from participant’s bra preferences and concerns were; comfort, support, aesthetics and fit.
- 90% of the focus group and interview participants expressed an interest in a bra prescription service.

\textbf{Chapter Three}

- A novel criterion was developed to select bras appropriate for assessment within a bra intervention. Applying the criteria lead to six everyday bras being chosen for use within a bra intervention.

\textbf{Chapter Four}

- The methods of measuring the four KPI’s were established. All four KPI’s should be measured subjectively using VAS’s. Support should be measured objectively using motion capture, assessing breast range of motion, velocity and acceleration. Objective bra fit should be assessed using the five-point best fit criteria.
Chapter Five

- To randomise the participants recruited to the RCT, a blocked randomisation design (permuted blocks of two) was determined with a 1:1 allocation
- The length of the monitoring period was determined to be 8 weeks with a 4 week follow up
- The outcome measures for use within the bra intervention were identified as; the PGIC (to measure the patient’s impression of the change in breast pain), NRS (breast pain intensity) and the SF-36 for measuring (QoL)
- A sample size of 180 (90 per group) was deemed necessary
- Blinding for group allocation was determined as appropriate with patients and clinicians blinded to this prior to consent

Chapter Six

- There were no statistically significant differences between the bra prescription group and the standard care group for the PGIC, breast pain intensity or QoL
- The physical component of QoL was significantly improved within the bra prescription group following the bra intervention.

Chapter Seven

- Recruitment and retention of participants was poor so the study was underpowered ($\beta = 0.56$)
- Key areas to evaluate to improve recruitment were; the prevalence of breast pain within the clinical cohort, whether the inclusion/exclusion criteria was restrictive to the recruitment of patients, interest in the bra intervention (specifically the prescription of a bra), barriers to participating in the bra intervention (amongst clinic patients with and without breast pain), and advice patients would like to receive within the bra intervention

Chapter Eight

- Breast pain was reported as the reason for attending the New Patient Breast Clinic by 18% of patients, but 62% of patients experienced some breast pain
- Less than half the patients (43%) at the New Patient Breast Clinic were interested in a bra prescription service. This may have been because 84% of patients did not report any problems with the bras they currently wear. This may affect adherence to standard care recommendations of obtaining a professional bra fit.
• A bra prescription service may need to be open to patients of all bra sizes

• Six non-clinical cohort (pregnancy/ breastfeeding, breast cancer, breast surgery, young adults, middle-aged adults and older adults) were more likely to take up the bra prescription service than the clinic cohort in Chapter Seven. This indicates the bra prescription service should be expanded to include non-clinical groups

• Contrary to the findings of Chapter Eight, experiencing breast pain and having a larger cup size were positive indicators of interest in the bra prescription service. This confirms these aspects of the inclusion criteria are appropriate for focussing the bra intervention and therefore these should remain the main criteria going forward

• The bra prescription service should be developed further to include other cohorts, to ensure it is an accessible service for all, as the location of the service was a barrier to participating for most cohorts and time was a barrier for the pregnant and breastfeeding and young adults groups

• The clinical cohort is an unusual group when compared to the non-clinical cohorts as a high percentage perceive they are wearing a well-fitting and supportive bra. This is despite 91% of those then tested who were in fact wearing a poorly fitting bra.

10.2 General Discussion

The studies completed for this thesis, using novel and robust methods, have progressed the work completed by Hadi (2000) and Wilson and Sellwood (1976), despite not fully replicating the same decrease in breast pain following a bra intervention. A new finding was established as the bra intervention showed an improvement in QoL. The methods in this thesis, can be applied to other cohorts, once their bra preferences and concerns have been identified. This allows for the bras to be selected using a novel selection criteria, which can be tailored for different specialist bras (e.g. sports bras, nursing bras and maternity bras). The bras selected within this thesis were chosen based on the constraint of the participants wanting to wear everyday bras, despite previous research identifying the effectiveness of sports bras (Hadi, 2000). Additionally, the bras chosen were representative of the current bras on the market, as previous research is dated (Wilson & Sellwood, 1976) and this thesis determined that one bra style will not fit or be the most appropriate for all women so a range of bra styles is needed.
The method of selecting the bras is applicable to other groups with some adjustments. The criteria established (Table 3.2) is specific to women with larger breasts who are experiencing breast pain. To use this approach outside of this cohort (such as pregnant or breastfeeding women), the criteria would need to be re-evaluated for its appropriateness. Firstly, once the group to be investigated is established, focus groups and interviews should be conducted to assess whether the key performance indicators for that group are the same or different to women with larger breasts and breast pain. Once these are established an assessment of the higher order themes within each key performance indicator can be completed. This will show which key performance indicators are objective or subjective. The objective higher order themes can then be used to establish the criteria. Once the criteria are determined, it firstly needs to be ordered so that the process of selecting bras is streamlined and efficient. In this thesis, Figure 3.1 shows the order that was chosen for the bra selection process. The same order can be chosen for a different group, but some criteria may be removed or others added. The next steps are to implement that criteria to establish a manageable groups of bras to be used within the intervention. Within this thesis the bra selection resulted in six bras, but the volume of bras that can be selected is dependent on the number that meet the criteria set.

Additionally, the activities and weightings for the bra prescription session were identified for this group but would need to be re-confirmed for a new group. The outcome measures were also identified using a review of the literature which determined the most appropriate method of showing the effectiveness of the bra intervention on breast pain and QoL, these outcome measures could be applied to any group. The overall steps to prescribe a bra using the method detailed within this thesis are presented in Figure 10.1.
10.3 Recommendations and future research

There are a number of areas to investigate before implementing the intervention or applying the intervention to a different cohort.

There was high proportion (84%) of patients who reported wearing well-fitting and supportive bras in the clinic cohort. This was unusual, as 91% of patients in the bra prescription group were wearing poorly fitting bras. It is possible that if patients thought they were wearing well-fitting and supportive bras, this may have negatively affected recruitment of patients into the bra intervention. It is therefore important that patients and clinicians gain an awareness of appropriate bras and the benefits they can provide because it may improve adherence and interest in the bra intervention. It is recommended that two educational programmes are developed, one for patients and one for clinicians to improve bra knowledge. The content within the educational programme should be multifactorial, covering the four KPI’s (comfort, support, fit and aesthetics) and these educational programmes should focus on how bras may be able to reduce breast pain. These educational programmes could run alongside the bra intervention and could be used as a
tool to recruit patients into the bra intervention. In developing these educational
programmes, research should investigate the most effective method of presenting this
material, whether this is face-to-face delivery, an online programme or leaflet-based.
Previous studies have used an education booklet to successfully improve bra knowledge
and fit in adolescents (McGhee et al., 2010) so it is possible this method would be
appropriate. Since the commencement of this thesis, there has been a National guidance
document issued to breast clinics which provide information on the appropriateness of well-
fitting bras. This document may go some way to educating clinicians in the importance of
bra fit, which may help recruiting patients for future studies in this area.

It is also recommended that an observational (single group) or patient-preference trial (semi-
randomised and preference based groups) should be undertaken to understand whether
the bra intervention itself can reduce breast pain for the clinical cohort. If the trial is
successful at demonstrating that breast pain can be reduced by a bra prescription, then a
full RCT should be undertaken. The results from an observational or patient-preference trial
could be utilised to promote the RCT and improve patient recruitment. In addition, the
observation or patient-preference trial could be run with an expanded inclusion criteria,
either by including patients with breast pain plus another benign symptom, and/or the bra
size criteria could be expanded. If a wider range of bra sizes are included, a further
qualitative study should examine the bra preferences and concerns of patients with smaller
breasts via focus groups and interviews. This is because the KPI's may be different for
patients with smaller breasts, and consequently this may affect the weightings used within
the bra prescription. The qualitative study should be completed prior to any observational
or patient-preference trial that includes patients with smaller breasts.

Alternative research could focus on developing the bra intervention for a different cohort of
women, for example women who are pregnant or breastfeeding. The first step to applying
the bra intervention would be to perform a qualitative study investigating the bra preferences
and concerns of the new cohort. The results from this qualitative study would identify the
KPI's for the new cohort and would allow for the bra selection criteria to be revised for
choosing appropriate bras for the new cohort, for example maternity and nursing bras for
pregnant or breastfeeding women. The bra prescription session itself may need to be
revised to include appropriate activities for the cohort and the weightings for prescribing a
bra may differ for a new cohort. Once the bras have been selected and the bra prescription
session is established, an observational or preference trial should be completed to
understand whether the bra prescription itself has the desired effect on breast pain and
QoL, before a full RCT is considered.
Once the effectiveness of the study has been determined, the intervention should undergo a process evaluation prior to its implementation. The Medical Research Council, who provided the guidance for developing complex interventions used within this thesis (Craig, Dieppe, Macintyre, Mitchie, et al., 2008), also provide a framework for completing a process evaluation (Moore et al., 2015). The purpose of this evaluation is to provide information for policy makers, on whether the intervention results will be reproducible and how an intervention may be implemented in a specific context (Moore et al., 2015). The framework covers three components: Implementation (what is implemented and how?), Mechanisms of Impact (how does the delivered intervention produce change?) and Context (how does context affect implementation and outcomes?) (Moore et al., 2015). Therefore, it is a recommendation of this thesis that once a full RCT has been rerun and the outcomes have been confirmed, the intervention should undergo a full process evaluation to provide evidence to policy makers on the possibility of implementation.

10.4 Conclusions

This thesis aimed to develop, pilot and evaluate a bra intervention for women with larger breasts who are experiencing breast pain for implementation within a NHS breast clinic, using MRC 2008 guidelines (Craig, Dieppe, Macintyre, Mitchie, et al., 2008).

Despite the bra being recommended by the NHS breast clinic as a treatment for breast pain, there has been no RCT which investigates the effectiveness of a bra at reducing the symptoms of breast pain. To develop an RCT bra intervention for this cohort, it was first important to understand the bra preferences and concerns of women with larger breasts who are experiencing breast pain. This was to ensure the bras chosen for use within the bra intervention were appropriate for the needs of the cohort and to increase the likelihood of patients adhering to wearing the bras during the intervention.

This study identified a number of bra performance indicators which were firstly used to develop a novel bra selection criterion, this narrowed down the substantial bra market to those bras that met the requirements of this cohort. Six everyday bras were chosen for use within the bra intervention. Of the bra performance indicators identified, comfort, support, fit and aesthetics, were of most importance and were used to inform the development of methods to individually assess, rank and prescribe an appropriate bra for each woman.

Following this, development of the intervention established the method of randomisation (blocked randomisation with permuted blocks of two, allocation ratio of 1:1), the length of follow-up (four and eight weeks), the outcome measures (PGIC, NRS and SF-36), the sample size (180 split 90/90) and the blinding procedures (group allocation for patients and clinicians).
The RCT bra prescription and intervention was then piloted and showed no significant differences between the bra prescription and standard care groups, but QoL (PCS) improved significantly over the eight weeks for the bra prescription group. The recruitment and retention of patients was poor. The RCT was therefore not implemented following the piloting phase and instead further evaluation was undertaken to determine if the bra intervention could be improved. The following aspects required further investigation; the prevalence of breast pain within the clinical cohort, the inclusion/exclusion criteria, interest in the bra intervention, and barriers to participating in the bra intervention. These aspects were investigated within the clinic cohort and other non-clinic cohorts. The number of patients reporting to the clinic with breast pain was lower than anticipated (18%) despite 62% of patients experiencing breast pain. Patients within the clinic cohort had less interest in the bra prescription service (43%) than non-clinic based cohorts, with a pregnancy and breastfeeding cohort being most likely to take up the bra prescription service (82%). It is possible that the patients within the clinic cohort reported lower interest, as 84% of them reported wearing well-fitting and supportive bras. This is despite 91% of patients within the bra prescription group in the RCT attending wearing a poorly fitting bra. In the non-clinic cohorts, experiencing breast pain and having larger breasts were indicators of interest in the bra prescription service. For the clinic and pregnancy/breastfeeding cohorts time constraint was the greatest barrier to participation in the bra prescription.

Although the bra intervention was not implemented, further development work should be completed as a result of this thesis to improve the bra intervention and to identify whether prescribing a bra can reduce breast pain. Through the development of the bra intervention for women with larger breasts who are experiencing breast pain, this thesis has also established a framework for prescribing a bra to any population of women. This thesis has also identified that this bra intervention has a positive effect on QoL.
11 References


Campbell, N. C., Murray, E., Darbyshire, J., Emery, J., Farmer, A., Griffiths, F., … Kinmonth,


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381. http://doi.org/10.1136/ard.37.4.378


References


References


References


197


Pearlman, M. D., & Griffin, J. L. (2010). Benign breast disease. Obstetrics and Gynecology,


affiliated with Shiraz University of Medical Sciences. *Journal of Health Science and Surveillance Systems, 4*(2), 4–9.


Zhou, J., Yu, W., & Ng, S.-P. (2012). Identifying effective design features of commercial

Appendix A: Breast Pain Survey completed by focus group and interview participants

Participant Number: ___________

Breast Pain

This section relates to your breast pain

1. When you experience breast pain, what is the intensity (on average): (Please mark the scale with a cross - X)

No Pain | Worst Possible Pain

2. When you are suffering from breast pain, what is the pattern of your breast pain? Please tick one from each group. If no words within that group represent your pain tick none of the above.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief</td>
<td>Rhythmic</td>
<td>Continuous</td>
</tr>
<tr>
<td>Momentary</td>
<td>Periodic</td>
<td>Steady</td>
</tr>
<tr>
<td>Transient</td>
<td>Intermittent</td>
<td>Constant</td>
</tr>
<tr>
<td>None of the above</td>
<td>None of the above</td>
<td>None of the above</td>
</tr>
</tbody>
</table>

3. How would you rate your breast pain overall? Tick one.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>□</td>
</tr>
<tr>
<td>Discomforting</td>
<td>□</td>
</tr>
<tr>
<td>Distressing</td>
<td>□</td>
</tr>
<tr>
<td>Horrible</td>
<td>□</td>
</tr>
<tr>
<td>Excruciating</td>
<td>□</td>
</tr>
</tbody>
</table>

4. On average, how many days do you experience breast pain per month?
5. Using the diagram above, **on what day of the menstrual cycle** is your breast pain worse? **Please write a number from 1 to 28 on the line below.** The red arrows indicate the start of menstruation.

6. At what **time of the day** is your breast pain **worse**? Please answer fully, for example, you may find your pain is worse in the mornings.

7. **How long** have you experienced breast pain for?

<table>
<thead>
<tr>
<th>Duration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 year</td>
<td>□</td>
</tr>
<tr>
<td>1 to 2 years</td>
<td>□</td>
</tr>
<tr>
<td>2 to 3 years</td>
<td>□</td>
</tr>
<tr>
<td>3 to 4 years</td>
<td>□</td>
</tr>
<tr>
<td>4 to 5 years</td>
<td>□</td>
</tr>
<tr>
<td>More than 5 years</td>
<td>□</td>
</tr>
</tbody>
</table>
8. Do you experience breast pain in your:

- [ ] Left Breast
- [ ] Right Breast
- [ ] Both Breasts

9. Using the diagram above, please identify the area you typically feel breast pain. Please tick all that apply.

- [ ] 1
- [ ] 2
- [ ] 3
- [ ] 4
- [ ] Nipple
10. On this page there is are six groups of words that **describe pain**, from each group please **tick one** descriptor if it applies to you – if **no words** in that group relate to your pain tick **none**.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flickering</td>
<td>Sharp</td>
</tr>
<tr>
<td>Quivering</td>
<td>Cutting</td>
</tr>
<tr>
<td>Pulsing</td>
<td>Lacerating</td>
</tr>
<tr>
<td>Throbbing</td>
<td>None</td>
</tr>
<tr>
<td>Beating</td>
<td></td>
</tr>
<tr>
<td>Pounding</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th>Group 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dull</td>
<td>Tender</td>
</tr>
<tr>
<td>Sore</td>
<td>Taut</td>
</tr>
<tr>
<td>Hurting</td>
<td>Raspaging</td>
</tr>
<tr>
<td>Aching</td>
<td>Splitting</td>
</tr>
<tr>
<td>Heavy</td>
<td>None</td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 3</th>
<th>Group 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricking</td>
<td>Jumping</td>
</tr>
<tr>
<td>Boring</td>
<td>Flashing</td>
</tr>
<tr>
<td>Drilling</td>
<td>Shooting</td>
</tr>
<tr>
<td>Stabbing</td>
<td>None</td>
</tr>
<tr>
<td>Piercing</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
Treatment of Breast Pain

*This section relates to the treatment of your breast pain*

9. Have you ever **used or participated in** any of the **treatments below**? *(Tick as many options as necessary)*

<table>
<thead>
<tr>
<th>Treatment</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamoxifen</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Toremifene</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Changing breast support</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Changing contraceptive medication</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Heat/cold application</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I have not tried any treatments</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

10a. Have you **experienced any side effects** of the treatment you have used?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>☐</td>
</tr>
<tr>
<td>No</td>
<td>☐</td>
</tr>
<tr>
<td>N/A</td>
<td>☐</td>
</tr>
</tbody>
</table>

b. If yes, **what side effects** did you have? *(Please describe)*

---

c. Are you **currently still using the treatments** you described above?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>☐</td>
</tr>
<tr>
<td>No</td>
<td>☐</td>
</tr>
</tbody>
</table>

11. What **do you think** makes your breast pain **worse**?
12. What **do you think** makes your breast pain **more manageable**?

**Bras and Bra Fitting**

13. What **type of bra** do you wear on a **daily basis**? Please tick all that apply.

   a. Underwired  
   b. Padded  
   c. Balconette  
   Plunge  
   b. Padded  
   Balconette  
   Plunge  
   Balconette  
   Plunge

14. When **were you last professionally measured** for bra size? Please tick one box.

   Last 3 months  
   Last 6 months  
   Within the last year  
   Over a year ago  
   Can’t remember  
   I have never been fitted

15. How would you rate your **knowledge (or awareness)** of the following breast health issues:

<table>
<thead>
<tr>
<th></th>
<th>Extremely Poor</th>
<th>Below Average</th>
<th>Average</th>
<th>Above Average</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bra Fit</strong></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>Appropriate</strong></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>Breast Support</strong></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>Breast Pain</strong></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

16. What is your **current bra size**?
Demographics

17. Please answer **yes or no** to the following statements

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>(If yes, please specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I have given birth to a child/children</td>
<td>☐</td>
<td>☐</td>
<td>How many?:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If NO, please go to statement c.</td>
</tr>
<tr>
<td>b. Did you experience breast pain before you had children?</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>c. I use contraceptive medication</td>
<td>☐</td>
<td>☐</td>
<td>What?</td>
</tr>
</tbody>
</table>

18. What is the **start date** of your most **recent or current period**?

19. What is your **age**?

Thank you participating in this survey
Appendix B: Protocol and Questions for Focus Groups and Interviews

Semi-Structured Focus Group: Protocol and Questions

Protocol:

- Participants come to the lab for introductions to each other, the researcher and an explanation of the focus group itself (for example, topics going to be covered, time it will take = up to 120 minutes).
- Participants will be explained the procedure of a focus group; sat in a circle, all contribute to discussion, audio recording and no talking over each other.
- Participants will be able to ask any questions about the session then sign the consent form and complete the focus group survey.
- Participants will be informed that the focus group would then begin.
- START RECORDING.

Questions:

1. What styles of bras do you typically wear?
   a. Any particular brands?
   b. Why these styles? Why these brands?
2. What features of a bra are most important to you?
   a. e.g. straps being thin, colour, support
   b. Why are they important?
3. Do you have any problems the bras you wear?
   a. e.g. they lack support, are uncomfortable?
   b. Do you think improving these problems would improve your breast pain?
   c. Why? / Why not?
4. Do you have problems purchasing bras?
   a. Why? / Why not?
5. Before purchasing bras do you get a professional bra fitting?
   a. Why? / Why not?
   b. (If yes) Do you inform your bra fitter that you experience breast pain?
6. Do you consider your pain when choosing bras?
   a. Why? / Why not?
7. Do you wear different bras, or do anything different relating to your bras, on days you have breast pain?
Appendix B

a. Why do you do this?
b. (If they wear different bras) How are the bras different?
c. Does your breast volume change over the month? Is this what influences a change in bra?

8. Do you think bras can reduce breast pain?
a. Why? / Why not?

9. Do you think any bra features can reduce pain?

10. Would you consider wearing sports bras on a daily basis if you knew they would decrease you breast pain?
a. Why? / Why not?

11. Do you think the bras that you wear make your breast pain worse or better?
a. How?

12. Do any activities make your breast pain worse?
a. What is it about these activities?

13. Would you see a benefit in a bra prescription service that would offer you an appropriate bra to help reduce your breast pain?
a. Why?/Why not?

IF YOU ARE CONCERNED ABOUT YOUR BREAST PAIN AT ALL PLEASE CONTACT YOUR GP.
Appendix C: An Investigation into the Reliability and Validity of the Visual Analogue Scale for measuring movement induced breast pain and bra comfort

14.1 Introduction

14.1.1 Reliability

Reliability relates to the consistency of a measurement or variable (Weir, 2005). The word 'reliability' can also be described by the terms 'repeatability', 'reproducibility', 'consistency', 'stability', 'concordance', 'precision' and 'agreement' (Atkinson & Nevill, 1998; Weir, 2005). The two types of reliability; absolute and relative, measure different components of reliability. Absolute reliability measures how agreeable an individual's test retest scores are and relative reliability investigates how individual's scores are relative to others within the group (Weir, 2005).

The t-test assesses systematic bias within the data, between the group mean of the data analysed (Atkinson & Nevill, 1998). This is useful in test-retest situations as it is hoped the data on the retest would have minimal random differences within the individuals (Atkinson & Nevill, 1998). But it should not be used as a single test for reliability, it should be incorporated with other tests that will show random variation (Atkinson & Nevill, 1998).

The Intraclass correlation (ICC) is a form of relative reliability. It assesses the between participant variability compared to sources of error (Weir, 2005). The ICC gives a correlation coefficient of between 0 and 1.0, with values closer to 1.0 representing minimal error (Weir, 2005). Two types of error are associated with the ICC; systematic and random, and whether these are measured depends on the type of ICC (there are six options) chosen to be assessed (Atkinson & Nevill, 1998; Weir, 2005). The two-way model is the most appropriate for test-retest data with a random factor associated with it. The random factor is for data that will be generalised (Weir, 2005). For example, the results of an assessment with a VAS may show the scale is reliable but the results would have to be generalised to be applied to other studies and participants. The criterion for what constitutes a 'good' or 'strong' ICC varies but a coefficient of; 0.7 to 0.8 is deemed 'questionable' and > 0.9 is 'strong' (Vincent, 1995). Nunnally and Bernstein (1994) suggested that the measurement error that is associated with the ICC is minimal in coefficients > 0.8. So within this study, the reliability coefficient needed for the VAS's to be deemed reliable, will be set at 0.8.

Previous research in the area of pain that used a VAS have had the positive descriptor (for example, no pain) on the left-hand side of the scale and the negative (for example, worst possible pain) on the right hand side (Bijur et al., 2001; Breivik et al., 2008; DeLoach et al., 1998; Gallagher, Liebman, & Bijur, 2001). This will be applied in this study to maintain consistency with previous research.
The Bland and Altman 95% limits of agreement assesses absolute reliability (Atkinson & Nevill, 1998). This method can be used to understand the level of agreement of individual test-retest scores within a population (Atkinson & Nevill, 1998). This method presents a range where 95% of the time participants scores will fall within these limits (Hopkins, 2000). This method can demonstrate the variability of scores between the test and retest and will show any bias in the results (Bland & Altman, 1995). An additional measurement of heteroscedasticity should be completed prior to undertaking the limits of agreement analysis to understand whether the mean is an influencing factor on the differences between the data (Atkinson & Nevill, 1998).

The VAS has been widely assessed for its reliability and validity within pain research (Bijur et al., 2001; DeLoach et al., 1998; Gallagher et al., 2001; Price, McGrath, Rafii, & Buckingham, 1983), but there is no research into the reliability and validity of a VAS for breast pain assessment. This is important to assess if a VAS is to be used in future breast research. Pain scales can be used within multidimensional tools such as surveys to add scope to the pain experience (Cleeland, 1991b; Melzack, 1983). Visual Analogue Scales are potentially difficult to use compared to other rating scales, especially if participants have never used them before so written or verbal instructions are advised (Breivik et al., 2008; Huskisson, 1974).

Breast pain is the primary measure with this thesis, with an overall aim to develop, pilot and evaluate a bra intervention for women with larger breasts who are experiencing breast pain for implementation within the NHS. Breast pain or discomfort is often a secondary measure in breast biomechanics literature after kinematic variables, such as breast displacement (Bridgman et al., 2010; Mason et al., 1999; Scurr et al., 2010; Scurr, White, Milligan, et al., 2011). Along with breast displacement, which has been found to reduce with increased breast support, breast pain has been found to reduce as the level of breast support increases compared to wearing no support during treadmill running (Mason et al., 1999; Scurr et al., 2010). This is often assessed using two breast support conditions (high and low support) and a bare-breasted condition (no support, Scurr et al., 2009, 2010; Scurr, White, & Hedger, 2011). Reliability should therefore be assessed across these three support conditions during treadmill running as this activity is known to elicit breast pain and a bra with high levels of support can influence the breast pain experienced.

In addition to pain, measurements of bra comfort are an important consideration within this thesis. Chan et al. (2001) reported that the typical bra has up to 20 components, comprising of both pattern pieces and accessories. The bra is therefore a complex piece of clothing (Chan et al., 2001). Considering the research by Mündermann et al., (2001), who assessed...
the comfort of shoe inserts based on multiple VAS, it is suggested that bra comfort should be assessed across bra components, rather than by one VAS measuring overall bra comfort.

14.1.2 Validity

Validity, is also an important factor to test when scales are developed (Litwin, 1995). Validity is how well a method measures what is it supposed to measure (Litwin, 1995). There are four main types of validity; face, content, criterion and construct (Litwin, 1995).

Criterion validity is a strong scientific measure of validity, and there are two types of criterion validity; concurrent and predictive (Litwin, 1995; Thomas, Nelson, & Silverman, 2011). Concurrent validity allows the new measure to be assessed against the 'gold standard' technique, accepted measure or criterion already established (Litwin, 1995; Thomas et al., 2011). Predictive validity is when a certain outcome or behaviour is predicted prior to the completion of a protocol (Litwin, 1995; Thomas et al., 2011). The VAS for breast pain can be assessed using predictive validity as it has been found previously that pain increases as breast support level decreases (Mason et al., 1999; Scurr et al., 2010). Bra comfort can also be assessed using this type of validity. The manufacturing differences of sports bras compared with everyday bras could suggest that the sports bra would be more comfortable than the everyday bra. Compared to an everyday bra, a sports bra is characteristically designed with coverings or padding on specific components such as the hook and eye and underwire to minimise irritation and improve comfort (Page & Steele, 1999). The straps of a sports bra are also often wider to distribute the force across the shoulder (Page & Steele, 1999). These factors indicate that a sports bra may demonstrate different comfort ratings than an everyday bra. Additionally, it is important to note that an increase in support has been found to correlate with an increase in bra comfort (Lawson & Lorentzen, 1990). Research has determined that a sports bra provides more support to the breasts (Mason et al., 1999; Scurr et al., 2009, 2010; Scurr, White, & Hedger, 2011) therefore this is rationale to suggest comfort will be higher in a sport bra. It is important to assess whether there are differences in the comfort levels of breast support as this can provide a method for assessing the validity of the VAS for bra comfort.

14.2 Aims and Hypotheses

14.2.1 Aims

The first aim of this study was to assess the reliability of a VAS for breast pain and bra comfort using a test-retest method.

The second aim of this study was to assess the predictive validity of the VAS to measure breast pain and bra comfort.
14.2.2 Hypotheses

Reliability

H₁: There will be no significant differences between the test-retest data for both breast pain and bra comfort.

H₂: There will be a strong significant ICC correlations between the test and retest pain scales across each of the three conditions.

H₃: There will be strong significant ICC correlation between the test and retest bra comfort scales.

H₄: Following tests for heteroscedasticity, the 95% limits of agreement will show the data falls within the 95% limits indicating agreement within the data for breast pain and with the data for bra comfort.

Validity

H₄: Breast pain will be significantly reduced in the high support condition compared to the low and no support conditions following a treadmill test.

H₅: Bra comfort will be significantly greater in the high support condition compared to the low support condition following a period of rest and a treadmill test.

14.3 Method

14.3.1 Participants and procedures

Participants were recruited using poster advertisement, promotion of the study on the University of Portsmouth’s intranet and by contacting previous breast health research volunteers who expressed an interested in participating in further studies. To participate in this study, participants had to be aged 18 years and over, and premenopausal. Exercise and health history questionnaires were completed by participants prior to participating in this study and written informed consent was obtained from each participant and kept within the project file.

Upon receiving institutional ethical approval, 13 females, who met the inclusion criteria, participated in this study (age 25 ± 5 years, height 1.66 ± 0.06 m, mass 64.7 ± 12.5 kg).

Participants were initially invited to the laboratory for a bra fitting, which was conducted by a professionally trained bra fitter with three years’ experience in retail.

14.3.2 Procedures

The bra fitting was completed using the five point best fit criteria (Table 14.1, White & Scurr, 2012; White, 2013). Fitted bra size, measured using the five point best fit criteria, ranged from 32 to 36 under band, A to F cup with a mode bra size of 32 C.
Table 14.1 Best-fit bra fitting criteria for everyday bras. Table taken from White, (2013)

<table>
<thead>
<tr>
<th>Step</th>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BAND</td>
<td>The band should fit firmly around the chest. It should not slide around as you move, but it should not be too tight to be uncomfortable, affect breathing or make flesh bulge over the band. The band should be level all the way around the chest.</td>
</tr>
<tr>
<td>2</td>
<td>CUP</td>
<td>The breasts should be enclosed within the cups, with no bulging or gaping at the top or sides. If the cup material is puckering then the cup size is probably too big.</td>
</tr>
<tr>
<td>3</td>
<td>UNDERWIRE</td>
<td>The underwire should follow the natural crease of the breasts and not rest on any breast tissue (in the centre, underneath the bra or under the arms). If the underwire is resting too far down the ribcage (i.e. where the ribcage gets slightly narrower) the band size is probably too small.</td>
</tr>
<tr>
<td>4</td>
<td>FRONT</td>
<td>The front of the bra (the lower edge under the breasts and between the cups if a separate piece exists) should sit flat against the body and not gape away from the chest. If the front of the bra is lifting away the cup size may need to be increased.</td>
</tr>
<tr>
<td>5</td>
<td>STRAPS</td>
<td>The shoulder straps should be adjusted to comfortably provide breast support without being too tight (i.e. digging into the skin). The main support for the breast should come from a firm band, not tight shoulder straps.</td>
</tr>
</tbody>
</table>

The high and low support bras were chosen as they have been previously used within breast biomechanics research, as an example of high and low breast support compared to bare-breasted running (Mills, Loveridge, et al., 2014a). The everyday bra (Figure 14.1 (a) or low support condition) used in this study was a Marks and Spencer® Non-Padded Underwired T-Shirt bra (78% polyamide and 22% elastane Lycra®). The bra used in the high support condition (Figure 13.1 (b) or sports bra) was a Shock Absorber® Run Bra (the UK’s best-selling branded encapsulation bra, 81% polyamide, 10% polyester and 9% elastane).

Figure 14.1: Bras used within this study, (a) low support (b) high support.
Participants were allowed to complete a warm up at a self-selected speed on the treadmill (H/P/Cosmos Mercury, Germany). After their warm up, participants were required to run on the treadmill for two minutes at 10 k.h\(^{-1}\) (Mason et al., 1999; Scurr et al., 2009), in three breast support conditions (no support, low support and high support). Participants were made aware that they could stop running at any time. One participant could not run at 10 k.h\(^{-1}\) for the duration of the run and in order to run for the whole two minutes ran at 9.0 k.h\(^{-1}\). Another participant could only run for 30 s due to excessive breast pain within the no bra condition.

To minimise order effect, the order of breast support conditions was randomised, using the RANDOM.org\textsuperscript{©} random sequence generator (White, 2013). For the two bra conditions (low support and high support), participants wore the bras at rest (prior to treadmill running) for 20 minutes, this time has been previously used as a duration of rest, prior to exercise, in clothing comfort research (Wong, Li, Yeung, & Lee, 2003). In this study it allowed for the breasts to settle in the bra and for any fitting adjustments to be made. During this time participants were asked to think about how comfortable the bra felt.

After each of the three running trials (no support, low support and high support) both breast pain intensity and bra comfort were measured on a 100 mm visual analogue scale. Verbal and written instructions on how to use the VAS were given to the participants (Breivik et al., 2008; Huskisson, 1974). Visual Analogue Scales were completed in the order shown in Figure 14.2 with a one minute gap between versions one and two of both the pain and comfort scales (Bijur et al., 2001). To minimise recall bias, prior to completion and straight after completion, the VAS’s were removed from sight of the participants.

**Order of Completion**

1. Pain V1
2. Comfort V1
3. Pain V2
4. Comfort V2

**Figure 14.2:** The order for the VAS for pain and bra comfort was completed after the treadmill run. A gap of one minute was maintained between completion of versions one and two of both the pain and comfort scales.

The descriptors for the pain scale were chosen (Figure 14.3) based on their use in previous research, either on VAS or Numerical Rating Scale (NRS) (Farrar et al., 2001; Hartrick,
‘Very comfortable’ was used as a positive descriptor within the research by Mündermann et al., (2001). ‘Very uncomfortable’ was chosen as the negative descriptor as it is the direct antonym to ‘very comfortable’. A thesaurus was used, to determine descriptors for use in version two of the comfort scales as previously used descriptors such as ‘extremely comfortable/uncomfortable’ did not seem directly comparable. The descriptors ‘really comfortable/uncomfortable’ were then chosen. Versions one and two of the scales had comparable but different descriptors e.g. no pain and painless. This was to ensure participants would not just respond to the second scale with an answer they thought was the same, the different descriptors initiated thought in the participants whilst asking the same thing.

Figure 14.3: Breast pain and comfort scales versions one and two.

Bra comfort was measured from eight bra features described in Chapter Four, section 4.1.1.

14.3.3 Data Analysis

Participant’s perceived ratings of pain and comfort were measured in millimetres, from the left hand side of the scale up to the point participants marked. The centre of the marked point was measured on all cases. Raw data were inputted into Microsoft Office Excel (2010), IBM SPSS Statistics version 21 and GraphPad Prism 6 software for reliability and validity statistical tests to be conducted.
The alpha value for statistical tests was $P = 0.05$. Non-parametric t-tests were conducted to investigate significant differences between the test and retest groups across all individuals. No significant difference would indicate that the data may be reliable. Test-retest data were analysed by an intra-class correlation (ICC) test. In an ICC, a perfect correlation (1.0) will only be found if the numbers in the retest are identical to the initial test, whereas the Pearson’s correlation will give a correlation coefficient of 1.0 if the results are perfectly correlated (for example, all scores in the retest are 10 mm higher) and not identical (Bijur et al., 2001). ICC coefficients of $> 0.9$ are considered strong (Currell & Jeukendrup, 2008) and between 0.7 and 0.8 the correlations are questionable (Currell & Jeukendrup, 2008).

Bland and Altman 95% limits of agreement were assessed via GraphPad. The differences between the test and re-test scores for individual participants was assessed against the average mean difference for each individual. Ninety-five percent confidence intervals were then placed against the data sets to assess how agreeable the data were.

Validity was assessed by a Wilcoxon signed-rank test to compare across the different breast support conditions; this was to assess whether breast pain reduced as support level increased. This test is for non-parametric data (Field, 2009, p. 552). The test is used to compare scores where the participants remain the same (matched pairs), and is centred around the differences between scores (from the test to retest) and the rank of that difference (Field, 2009).

14.4 Results

14.4.1 Pain

14.4.1.1 Reliability

Three breast support conditions (no support, low support and high support) resulted in each participant (n=13) reporting their pain three times leading to 39 matched pairs for pain ratings. Wilcoxon signed rank tests showed no significant difference ($P = > 0.05$) between the test and retest data, indicating that the data may be reliable. Reliability statistics showed a strong significant ICC of $> 0.91$ ($P = < 0.05$) and the Bland-Altman plot indicated that 95% of the data fell between -20 mm and +23 mm with a bias of +2 (Figure 14.4).
Figure 14.4: a) Distribution of data for breast pain following a one minute test-retest, b) Bland-Altman plot for 95% limits of agreement for breast pain across all conditions (n = 13).

Figure 14.5. shows for all conditions that over 50% of participants were within 5 mm of their first rating on their test-retest for breast pain following running.
Reliability was highest in the no support (NS) condition (ICC = 0.90) although all ICC scores were significant (Table 14.2).

Table 14.2: Reliability statistics based on the ICC and Bland-Altman 95% limits of agreement.

<table>
<thead>
<tr>
<th></th>
<th>Average (± SD) mm</th>
<th>ICC</th>
<th>Bland-Altman 95% Limits of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Version One</td>
<td>Version Two</td>
<td>Upper</td>
</tr>
<tr>
<td>No Support</td>
<td>37.4 (27.8)</td>
<td>37.3 (31.8)</td>
<td>0.90*</td>
</tr>
<tr>
<td>Low Support</td>
<td>21.4 (24.6)</td>
<td>19.1 (18.8)</td>
<td>0.85*</td>
</tr>
<tr>
<td>High Support</td>
<td>5.6 (9.9)</td>
<td>2.9 (5.6)</td>
<td>0.69*</td>
</tr>
</tbody>
</table>

* Denotes significant result (p = < 0.05)

14.4.1.2 Validity

The pain experienced by participants in the no support condition was significantly higher than the low support (Z = -2.578, P = 0.007) and high support conditions (Z = -2.845, P =
Participants also rated their pain significantly higher ($Z = -2.100, \ P = 0.039$) during the low support condition compared to the high support.

### 14.4.2 Comfort

#### 14.4.2.1 Reliability

The eight measurements of bra comfort were assessed in each bra condition (low and high support), resulting in 207 matched pairs across the test and retest for 13 participants. Wilcoxon Signed Rank tests showed no significant difference between the test and retest groupings ($P = > 0.05$). An ICC of $> 0.87$ ($P = < 0.05$) showed a moderately strong significant correlation and the Bland-Altman plots showed 95% limits of -21 mm and +23 mm (Figure 14.6).
Figure 14.6: a) Distribution of data for bra comfort following a one minute test-retest, b) Bland-Altman plot for 95% limits of agreement for bra comfort across all bra components and two bra conditions (LS & HS) (n = 13).

For all cases except the under band (back) over 50% of participants were within 5 mm of their first rating of bra comfort (test) when completing the second measurement (retest) (Figure 14.7). It is also to be noted that by the category 11 to 15 mm all measured variables have over 80% of the data within 15 mm following the test and retest.
Figure 14.7: Distribution of scores across the eight bra components for bra comfort. Reliability of the bra comfort scales was also assessed using the ICC and Bland Altman 95% limits of agreement for each bra component in the low and high support individually (Table 14.3). There was a weak correlation between the test and retest VAS’s in the under band (back) for the low support (ICC = 0.60) and for the straps (ICC = 0.74), side (ICC = 0.71) and hook and eye (ICC = 0.75) of the high support condition. The Bland-Altman limits show that the fabric for both the low support and high support conditions had the smallest variability between the test and retest scores.
### Table 14.3: Reliability statistics for each bra component measured on the bra comfort visual analogue scale.

<table>
<thead>
<tr>
<th>Bra Component</th>
<th>Version One</th>
<th>Version Two</th>
<th>ICC</th>
<th>Bland Altman 95% Limits of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average (SD) mm</td>
<td></td>
<td></td>
<td>Upper</td>
</tr>
<tr>
<td>Low Support</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Straps</td>
<td>22 (22)</td>
<td>24 (24)</td>
<td>0.90*</td>
<td>19</td>
</tr>
<tr>
<td>Underband (Back)</td>
<td>16 (11)</td>
<td>23 (19)</td>
<td>0.60*</td>
<td>18</td>
</tr>
<tr>
<td>Centre Piece</td>
<td>24 (24)</td>
<td>28 (25)</td>
<td>0.93*</td>
<td>14</td>
</tr>
<tr>
<td>Underwire (under band front)</td>
<td>23 (22)</td>
<td>26 (25)</td>
<td>0.86*</td>
<td>21</td>
</tr>
<tr>
<td>Side</td>
<td>22 (27)</td>
<td>16 (16)</td>
<td>0.83*</td>
<td>30</td>
</tr>
<tr>
<td>Hook and Eye</td>
<td>17 (23)</td>
<td>22 (23)</td>
<td>0.82*</td>
<td>21</td>
</tr>
<tr>
<td>Cups</td>
<td>23 (26)</td>
<td>24 (26)</td>
<td>0.97*</td>
<td>13</td>
</tr>
<tr>
<td>Fabric</td>
<td>13 (17)</td>
<td>13 (18)</td>
<td>0.96*</td>
<td>10</td>
</tr>
<tr>
<td>High Support</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Straps</td>
<td>37 (29)</td>
<td>28 (25)</td>
<td>0.74*</td>
<td>46</td>
</tr>
<tr>
<td>Underband (Back)</td>
<td>22 (18)</td>
<td>19 (21)</td>
<td>0.93*</td>
<td>17</td>
</tr>
<tr>
<td>Centre Piece</td>
<td>16 (23)</td>
<td>12 (17)</td>
<td>0.92*</td>
<td>18</td>
</tr>
<tr>
<td>Underwire (under band front)</td>
<td>18 (18)</td>
<td>15 (17)</td>
<td>0.91*</td>
<td>17</td>
</tr>
<tr>
<td>Side</td>
<td>1 (14)</td>
<td>10 (11)</td>
<td>0.71*</td>
<td>22</td>
</tr>
<tr>
<td>Hook and Eye</td>
<td>20 (28)</td>
<td>13 (19)</td>
<td>0.75*</td>
<td>39</td>
</tr>
<tr>
<td>Cups</td>
<td>15 (26)</td>
<td>12 (24)</td>
<td>0.97*</td>
<td>15</td>
</tr>
<tr>
<td>Fabric</td>
<td>16 (23)</td>
<td>13 (23)</td>
<td>0.96*</td>
<td>10</td>
</tr>
</tbody>
</table>

#### 14.4.2.2 Validity

The Wilcoxon signed rank test (Table 14.4, for version one) showed that there was no significant difference ($p > 0.05$) between the ratings of bra comfort across each bra component for the low and high support conditions. Directionality of the results was varied showing that perception of comfort in the low and high support conditions often interchanged.
Table 14.4: Results of the Wilcoxon signed rank test for validating the bra comfort scale (n = 13). Due to missing data, only 12 participants were compared for the component 'centre-piece'.

<table>
<thead>
<tr>
<th>Bra Component</th>
<th>Average ± SD (mm)</th>
<th>Z</th>
<th>P</th>
<th>Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Support</td>
<td>Low Support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Straps</td>
<td>37 ± 29</td>
<td>22 ± 23</td>
<td>-1.687</td>
<td>0.960</td>
</tr>
<tr>
<td>Underband (Back)</td>
<td>22 ± 18</td>
<td>16 ± 11</td>
<td>-1.255</td>
<td>0.233</td>
</tr>
<tr>
<td>Centre Piece</td>
<td>16 ± 23</td>
<td>24 ± 24</td>
<td>-0.942</td>
<td>0.370</td>
</tr>
<tr>
<td>Underwire/Underband (Front)</td>
<td>18 ± 18</td>
<td>23 ± 22</td>
<td>-0.769</td>
<td>0.465</td>
</tr>
<tr>
<td>Side</td>
<td>13 ± 14</td>
<td>22 ± 26</td>
<td>-0.868</td>
<td>0.414</td>
</tr>
<tr>
<td>Hook and Eye</td>
<td>20 ± 28</td>
<td>17 ± 23</td>
<td>-0.078</td>
<td>0.970</td>
</tr>
<tr>
<td>Cups</td>
<td>15 ± 26</td>
<td>23 ± 26</td>
<td>-1.766</td>
<td>0.082</td>
</tr>
<tr>
<td>Fabric</td>
<td>16 ± 23</td>
<td>13 ± 17</td>
<td>-0.714</td>
<td>0.510</td>
</tr>
</tbody>
</table>

14.5 Discussion

The aim of this study was to assess the reliability and validity of VAS’s for measuring breast pain intensity and bra comfort and was the first study to do so in breast pain research. The results showed that the VAS is a reliable and valid tool for measuring movement-induced breast pain across three breast support conditions following a treadmill running test. The VAS was also a reliable tool for measuring bra comfort; however, it was not valid. The Wilcoxon signed rank test gave an indication of the reliability of the VAS for both pain and comfort as there were no significant differences found within the group means, this accepts hypothesis one.

Previous research has shown that the VAS is a reliable tool for measuring pain with ICC coefficients of 0.95 and 0.98 being found in test-retest research where the retest occurs after a one minute delay (Bijur et al., 2001; Gallagher, Bijur, Latimer, & Silver, 2002). This value is directly comparable with the correlation coefficient seen after the test-retest for the no support condition (r = 0.90). Although the correlation coefficients were lower for the low and high support conditions (r = 0.85 and r = 0.68), which could possibly explained by the heteroscedasticity of the data, the low support condition values still represents a moderate strength ICC result (Currell & Jeukendrup, 2008). The overall ICC value was strong with a significant ICC of 0.91. The 95% limits of agreement for the VAS taken at one minute apart
Appendix C

at -20 mm and +23 mm had a bias close to 0 which indicates there was no trend for the results to be skewed in a particular direction. For example, the retest VAS was not consistently marked higher than the test VAS. The distribution of scores (Figure 13.5b) showed that in the bare-breasted and high support conditions almost 70% of participants were within 5 mm of the first rating of pain when they retested the scale, this percentage was just over 50% for the low support condition which is similar to the distribution found in DeLoach et al. (1998).

As found in previous breast biomechanics research (Mason et al., 1999; Scurr et al., 2010), breast support significantly affected the intensity of breast pain felt by participants. In agreement with this, and accepting hypothesis two, the no support condition was significantly \( (p = 0.007) \) more painful than the low support and high support, and the low support was also significantly \( (p = 0.039) \) more painful than the high support condition. Wearing increased levels of breast support is known to be a method of reducing breast pain during exercise but it has also been found to help reduce clinically significant breast pain and is widely recommended as a non-pharmacological treatment for these women (Hadi, 2000; Mason et al., 1999; Wilson & Sellwood, 1976). This demonstrates the VAS is a valid tool for assessing breast pain as in accordance with previous research. Tests showed that the VAS can differentiate levels of pain as breast support level changes, supporting the hypotheses of this study.

Bra comfort was assessed across eight bra components found typically on the bra (Chan et al., 2001). This allowed for a detailed assessment of comfort between the two bra support conditions as the low and high support bras were different in fabric properties and design. The reliability of the VAS for bra comfort has not been previously assessed. For the most part a moderate and strong ICC correlation (> 0.80) was seen in both the high and low support conditions between the test and retest measurements (Currell & Jeukendrup, 2008). A few components of the bra (Low Support = under band (back), High Support = straps, side and hook and eye) had questionable ICC’s between the test and retest measurements, as they were lower than the recommended 0.80. Hypothesis 3 is therefore partially accepted.

A limitation of this study is that the sample size was low; an increase in participant numbers may have helped to increase the correlation coefficient of these bra components. Interpreting the Bland-Altman plot and the distribution of scores (Figure 14.7b), over 50% of participants were within 5 mm of their first rating of bra comfort when rating comfort a second time. This value increases to 80 % within 15 mm of the first comfort rating. This
suggests that there is good agreement of scores from the test to retest and indicates that participants rated their comfort twice with minimal variability, accepting hypothesis four.

In assessing the validity of the VAS for bra comfort; it was hypothesised that the high support bra would be perceived as more comfortable during running than the low support bra due to design differences such as extra padding, wider straps to distribute the force over the shoulders, (Page & Steele, 1999) and the association of increased support leading to increase comfort (Lawson & Lorentzen, 1990). However, the low support bra was considered more comfortable by the participants for the straps, under-band (back) and the fabric when compared to the high support bra. From the remaining components there was no significant difference. The straps, although wider on the high support bra, were not considered more comfortable than the straps on the low support bra. This showed disagreement to previous research regarding the dissipation of force, but this may be attributed to the racer back design of the high support bra (Page & Steele, 1999). The racer back design pulls the straps into the centre of the back; this is has been reported to make the bra feel more supportive (Page & Steele, 1999), but could be seen as uncomfortable for those who are not used to wearing their bra straps in this orientation. The fabric on the low support bra was also deemed more comfortable, possibly due to the increased levels of elastane within this bra. Elastane is a stretch fabric and is often found in clothing that requires close fitting to the body and high levels of comfort (e.g. tights, sportswear, swimwear) (Senthilkumar et al., 2011). The purpose of a sports bra is to minimise excessive breast motion therefore they are often designed with firmer fabrics (Zhou, Yu, & Ng, 2012).

These findings pose the question; can a VAS ever be validated as a measure for bra comfort? Comfort is highly subjective (Miller et al., 2000). It has been found within shoe insert research conducted by Mündermann et al. (2001) that perceptions of comfort varied and it was suggested that individual results for comfort should be investigated (not group means) when looking at perceptions of shoe insert comfort. This will be applied within this thesis. A larger number of participants may have helped to confirm the findings found. As a result the assessment for validating comfort cannot be completed using the methods chosen, but within-participant reliability was high, promoting the use of the VAS within this research.

14.6 Conclusions

This study was the first to assess the reliability and validity of a VAS to measure breast pain and bra comfort. The results of this study show that a VAS is a reliable tool for measuring both breast pain intensity and bra comfort during exercise. The VAS is also a valid tool for measuring breast pain as it is able to distinguish a difference in pain intensity between bra
conditions. Although the VAS was not valid for measuring comfort due to varying individual differences, due to its high reliability it will be used within further chapters of this thesis. It is recommended that, now the VAS has been validated and assessed for reliability, the VAS should be the rating scale used within this thesis for pain and comfort measurement.
Appendix D: Medical outcomes study 36-item short form survey (sf-36) – quality of life survey

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Health Status</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>1</td>
</tr>
<tr>
<td>Very Good</td>
<td>2</td>
</tr>
<tr>
<td>Good</td>
<td>3</td>
</tr>
<tr>
<td>Fair</td>
<td>4</td>
</tr>
<tr>
<td>Poor</td>
<td>5</td>
</tr>
</tbody>
</table>

2. Compared to one year ago, how would you rate your health in general now:

<table>
<thead>
<tr>
<th>Health Status</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much better now than one year ago</td>
<td>1</td>
</tr>
<tr>
<td>Somewhat better now than one year ago</td>
<td>2</td>
</tr>
<tr>
<td>About the same</td>
<td>3</td>
</tr>
<tr>
<td>Somewhat worse now than one year ago</td>
<td>4</td>
</tr>
<tr>
<td>Much worse now than one year ago</td>
<td>5</td>
</tr>
</tbody>
</table>

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle One Number on Each Line)

3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports

<table>
<thead>
<tr>
<th>Yes, Limited a Lot</th>
<th>Yes, Limited a Little</th>
<th>No, Not limited at All</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]</td>
<td>[2]</td>
<td>[3]</td>
</tr>
</tbody>
</table>

4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

<table>
<thead>
<tr>
<th>Yes, Limited a Lot</th>
<th>Yes, Limited a Little</th>
<th>No, Not limited at All</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]</td>
<td>[2]</td>
<td>[3]</td>
</tr>
</tbody>
</table>

5. Lifting or carrying groceries

<table>
<thead>
<tr>
<th>Yes, Limited a Lot</th>
<th>Yes, Limited a Little</th>
<th>No, Not limited at All</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]</td>
<td>[2]</td>
<td>[3]</td>
</tr>
</tbody>
</table>

6. Climbing **several** flights of stairs

<table>
<thead>
<tr>
<th>Yes, Limited a Lot</th>
<th>Yes, Limited a Little</th>
<th>No, Not limited at All</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]</td>
<td>[2]</td>
<td>[3]</td>
</tr>
</tbody>
</table>

---

3 The 36-Item Health Survey was developed at RAND as part of the Medical Outcomes Study
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(Circle One Number on Each Line)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. Cut down the amount of time you spent on work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>14. Accomplished less than you would like</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>15. Were limited in the kind of work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>16. Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>17. Cut down the amount of time you spent on work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>18. Accomplished less than you would like</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>19. Didn't do work or other activities as carefully as usual</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(Circle One Number)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>1</td>
</tr>
<tr>
<td>Slightly</td>
<td>2</td>
</tr>
<tr>
<td>Moderately</td>
<td>3</td>
</tr>
<tr>
<td>Quite a bit</td>
<td>4</td>
</tr>
<tr>
<td>Extremely</td>
<td>5</td>
</tr>
</tbody>
</table>

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1</td>
</tr>
<tr>
<td>Very mild</td>
<td>2</td>
</tr>
<tr>
<td>Mild</td>
<td>3</td>
</tr>
<tr>
<td>Moderate</td>
<td>4</td>
</tr>
<tr>
<td>Severe</td>
<td>5</td>
</tr>
<tr>
<td>Very Severe</td>
<td>6</td>
</tr>
</tbody>
</table>

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>1</td>
</tr>
<tr>
<td>A little bit</td>
<td>2</td>
</tr>
<tr>
<td>Moderately</td>
<td>3</td>
</tr>
<tr>
<td>Quite a bit</td>
<td>4</td>
</tr>
<tr>
<td>Extremely</td>
<td>5</td>
</tr>
</tbody>
</table>

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.
How much of the time during the **past 4 weeks** . . .

*(Circle One Number on Each Line)*

<table>
<thead>
<tr>
<th>Question</th>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>A Good Bit of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>23. Did you feel full of pep?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>24. Have you been a very nervous person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>25. Have you felt so down in the dumps that nothing could cheer you up?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>26. Have you felt calm and peaceful?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>27. Did you have a lot of energy?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>28. Have you felt downhearted and blue?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>29. Did you feel worn out?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>30. Have you been a happy person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>31. Did you feel tired?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

*(Circle One Number)*

<table>
<thead>
<tr>
<th>All of the time</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most of the time</td>
<td>2</td>
</tr>
<tr>
<td>Some of the time</td>
<td>3</td>
</tr>
<tr>
<td>A little of the time</td>
<td>4</td>
</tr>
</tbody>
</table>
How TRUE or FALSE is each of the following statements for you.

*(Circle One Number on Each Line)*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don't Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td>33. I seem to get sick a little easier than other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>34. I am as healthy as anybody I know</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>35. I expect my health to get worse</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>36. My health is excellent</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

In order to compare your surveys now with the surveys you complete in four and eight week time. We need to assign you a participant number. Please can you provide your name so we can assign you your number:

Please Write Your Name: _____________________________________

This information will be detached from the survey and shredded once the participant number is assigned. The contact sheet you have also filled out will allow the University of Portsmouth Researcher to contact you regarding the remainder of the study.

PLEASE REMOVE FROM SURVEY ONCE PARTICIPANT NUMBER ASSIGNED
Appendix E: An investigation of reliability and validity of a new diary and survey for the assessment of breast pain.

16.1 Introduction

16.1.1 Breast Pain Surveys

A Breast Pain Questionnaire was developed from the short form McGill Pain Questionnaire by Khan and Apkarian (2002a, 2002b). There are six stages to developing measures; item generation, questionnaire administration, initial item reduction, confirmatory factor analysis, convergent/discriminatory validity and replication. The Breast Pain Questionnaire was rigorously assessed by Khan and Apkarian, and this assessment included a Principle Components Factor Analysis. The study demonstrated that the Breast Pain Questionnaire used the validated aspects of the short form McGill Pain Questionnaire and was able to confirm the current clinical impression of breast pain, demonstrating the validity of the Breast Pain Questionnaire (Khan & Apkarian, 2002a).

There is an opportunity to further the Breast Pain Questionnaire, to gain a more comprehensive view of the breast pain experience to ensure it meets the specific aims of this thesis and the bra intervention. For example, the Breast Pain Questionnaire asks respondents to list any medications they currently take for breast pain, yet there is little opportunity for other treatments to be listed if they EPO in the list of medications since it is available over the counter. Evening Primrose Oil is a common recommendation by practitioners to breast pain sufferers. It also discounts the use of any homeopathic remedies or any changes to lifestyle that may have been made previously to aid breast pain. It is important for this thesis to understand further treatments as these may be confounding factors in the outcomes.

16.1.2 Breast Pain Diaries

The daily diary is a form of Ecological Momentary Assessment (EMA) that can be used as a method of self-report for reporting breast pain. The benefits of using EMA as method of data collection is that the data is collected in the 'real world' (Shiffman et al., 2008), participants completing a breast pain diary would complete the diary at home and not in the laboratory setting. Additionally, the diary method collects data frequently meaning the recall necessary to complete the diary is based on the past day, making it short (Shiffman et al., 2008). Other methods such as surveys may be collected less frequently but require a longer period of recall which may alter the results obtained. The diary method allows for data to be collected over time providing a more 'ecologically valid' method of data collection, in the case of a breast pain diary, this allows for fluctuations in breast pain to be seen including
the intensity of pain and number of days of breast pain per month. A breast pain questionnaire in this instance would only provide estimates of this based on recall.

The Cardiff breast pain chart (Mansel, 1994) is the most frequently used breast pain diary appearing in many breast pain studies. The chart allows participants to shade squares (representing each day) to the degree of breast pain they are experiencing (no pain, mild or severe). Respondents are also required to note the start and duration of menstruation. This allows for three aspects of cyclical breast pain to be measured; the intensity, number of days of breast pain and the menstrual cycle. There are additional factors that could be considered when assessing breast pain; typically pain is measured on a rating scale (0-10) and as discussed in previous chapters can take a number of forms. This type of scale provides an increased level of discrimination between days of breast pain than the previously used intensity ratings in the Cardiff breast pain chart. Additionally, the McGill Pain Questionnaire has a present pain index (PPI) which has been used within a breast pain questionnaire (Khan & Apkarian, 2002a) to give an overall evaluation of breast pain. This assessment can allow for a descriptor (no pain, mild, discomforting, distressing, horrible and excruciating) to be applied to the intensity rating given. Furthermore an assessment of the number of days of pain could be complimented by an understanding of the frequency of pain during the day and this can also compliment the intensity ratings – this allows for further interpretation of the data (for example whether a rating of 8 on a rating scale correlates to one occasion of pain during the day or whether this intensity occurred all day).

16.1.3 Assessing new methods of data collection

The definition of reliability and validity are presented in Appendix C. Appendix C also presents methods of assessing both reliability and validity. Within survey reliability assessment test-retest is a form of reliability test which has been used to assess the SF-36, the QoL survey which has been used to assess QoL in the intervention study (Ware, Jr., Kosinski, & Keller, 1996). Therefore this method of assessing reliability is appropriate for the survey within this thesis. It is important for a survey to be reliable and valid. It is important that absolute reliability is high in the survey within this thesis, as this demonstrates that within an individual, the results are reliable (Weir, 2005). Ultimately, within this thesis, the individual improvements are most important, rather than the group as a whole. Validity of surveys is also important, as it shows that the survey is measuring what it is designed to measure (Litwin, 1995). The Breast Pain Questionnaire and other measures of pain such as the visual analogue scale or the numerical rating scale, have been widely assessed for validity, through previous studies and research.
One previous study investigated the reliability and validity of a diary for women with premenstrual syndrome (Freeman, DeRubeis, & Rickels, 1996). Women with premenstrual syndrome have chronic symptoms that occur during the luteal phase of the menstrual cycle (between days 14 to 28) (Freeman et al., 1996). Symptoms can be emotional (e.g. irritability, anxiety and mood swings) and/or physical (e.g. abdominal cramps, bloating and weight gain) and this can also include breast pain (Hamaideh, Al-Ashram, & Al-Modallal, 2013). Cyclical breast pain has its similarities to premenstrual syndrome as it peaks during the luteal phase of the menstrual cycle. This is followed by a reduction during menstruation and in the follicular stage of the cycle. Considering this, the study by Freeman et al. (1996) utilised this pattern to investigate the reliability and validity of a premenstrual diary, comparing the pre-menstrual (6 days prior to menstruation) and post-menstrual (6 days post-menstruation) phases of a group of participants diagnosed with premenstrual syndrome compared to a control group (no premenstrual syndrome). A within-participant design could be completed using participants who experience some level of cyclical breast pain, as it is known that this pain would be higher in the luteal phase prior to menstruation compared to the follicular post menstruation phase.

Additionally to the methods presented in Appendix C, internal consistency is also another measurement (of reliability) that has previously been used in diary studies (Freeman et al., 1996). Internal consistency looks at how well an item (or a question in this case) can predict or indicate other items within the instrument (diary in this case) (DeVon et al., 2007). This is typically assessed using the Cronbach’s α value. An α value > 0.9 is considered to show high internal consistency within the items of the diary. Previous diary research found high internal consistency (Freeman et al., 1996).

This study therefore aims to develop a Breast Pain Survey and a Breast Pain Diary for use within this thesis. The outline of the first stage of this development is below (Figure 16.1):
16.2 Part A: The development of a Breast Pain Survey and breast pain diary and initial tests of reliability and validity

16.2.1 Aims and Hypotheses

There were seven aims for Part A of this Chapter;

Aim 1: To develop a new Breast Pain Survey and a Breast Pain Diary based on the Cardiff Breast Pain Chart (Mansel, 1994) and additional breast and pain surveys

Aim 2: To assess the reliability of a new Breast Pain Survey

Aim 3: To assess participant compliance using a breast pain diary.

Aim 4: To assess the validity of a new breast pain diary by comparing the pre- and post-menstruation phases of the menstrual cycle.

Aim 5: To assess the reliability of a new breast pain diary

Aim 6: To assess whether the new breast pain diary is considered an acceptable method for monitoring acute pain using some evaluative questions within the Breast Pain Survey.
Hypotheses

\( H_1 \): The ICC for test-retest reliability will show high correlation (\( \leq 0.9 \)) between the test-retest surveys.

\( H_2 \): There will be a significant difference (\( p < 0.05 \)) between the pain experienced between the post-menstrual and pre-menstrual phases of the breast pain diary, with the pre-menstrual phase scoring significantly higher for intensity, frequency and overall pain experience.

\( H_3 \): The Cronbach’s \( \alpha \), will show that the diary has high internal consistency (\( \geq 0.9 \)) for weeks one, two, three and four of the menstrual cycle. The ICC will show high reliability for the test retest (\( \geq 0.9 \)).

16.2.2 Methods

16.2.2.1 Survey Development

Previous surveys have looked at whole body pain on a multidimensional level (Cleeland, 1991a; Melzack, 1983). The Breast Pain Questionnaire (Khan & Apkarian, 2002a) was developed and implemented as a survey specifically for breast pain, both non-cyclical and cyclical, however, this was used as a diagnostic tool for clinical settings (Khan & Apkarian, 2002a). There are six stages which are linked with the process of developing scales for new surveys, these are; item generation, questionnaire administration, initial item reduction, confirmatory factor analysis, convergent/discriminatory factor analysis and replication (Hinkin, 1995). The survey developed in this chapter will be based on questions from the Breast Pain Questionnaire (Khan & Apkarian, 2002b) therefore, items within the survey are not being generated from scratch, but merely adapted from a previously validated survey for breast pain.

The Breast Pain Survey has been developed as a method of assessing the level of cyclical breast pain being experienced by an individual. The formatting of the survey is based on the advice within the literature of questionnaire design, which guides on aspects such as layout, font sizing and question ordering (Bradburn et al., 2004). The survey incorporates adapted design and structural features and questions from the McGill Pain Questionnaire (Melzack, 1983) and the Breast Pain Questionnaire (Khan & Apkarian, 2002a). A number of question styles were used to develop the survey incorporating both open and closed questions to get as much detail from participants about their breast pain experiences².

---

² During ethical review it was suggested that for the pain descriptors from the McGill Pain Questionnaire that the word 'lancinating may not be understood by many participants as it is not a
The question format has been varied to maintain interest from the respondents as this has been suggested to prevent answers to questions being based on repetition (Bradburn et al., 2004). The main focus of this research is how breast support can treat cyclical breast pain suffered by women with larger breasts, due to this the topics of breast pain and treating breast pain were placed at the forefront of the survey, as this allowed the most important data to be collected first (Bradburn et al., 2004).

Demographics were added as the last section of this survey, as it is suggested that ‘non-threatening’ or ‘boring’ questions should not be at the front of the survey as these questions may dissuade respondents from completing it (Bradburn et al., 2004). Demographic information is not necessarily seen as ‘threatening’ or ‘boring’ however often they questions are personal and may not want to be answered straight away. There are 23 questions in total (Appendix F). The next stage of survey development is to administer the questionnaire.

16.2.2.2 Diary Development

The diary was developed to show acute daily changes in breast pain, with the anticipation of it being used for the intervention study. Before developing the diary, there were two factors to be considered; firstly the method of collecting the data and secondly the content. As participants will be completing the diary daily, it was important to minimise what participants had to answer on days they did not suffer from breast pain. The online/mobile format of the diary using Google Forms allows for navigation based on the answers given. Therefore, the diary was created to initially ask participants; their participant number, the date and ask whether they were suffering from breast pain on this day. If participants answered yes they would be navigated through the further detailed questions about their pain, if participants answered no, they would be navigated to the final page which simply asked them whether they were currently menstruating. This was decided upon in order to minimise any boredom which could come about from filling out the diary daily and to use minimal amounts of participants’ time.

Evaluating the literature on the subject of paper versus electronic diaries, the compliance and adherence rates of electronic diaries are much greater than the paper form of diaries (Kuntsche & Labhart, 2013; Shiffman et al., 2008; Stone, Shiffman, Schwartz, Broderick, & Hufford, 2002). From this information it would be ideal, if electronic forms of diary implementation were used in this research. Initial thoughts suggested that a mobile application would be the best option for data collection. In the first instance, due to the term used in general conversation. It was suggested that this word was changed to piercing. This change was made.
researcher having no prior existing knowledge of mobile application development or computer coding, both internal to the University of Portsmouth and external mobile application developers were contacted for quotes and information relating to the development, during January 2014. An application specification was attached to emails to allow developers to understand the requirements of the application and estimate time and cost from this. Phone and email conversations occurred between developers and the researcher over a period of two weeks in January 2014. From these conversations app development was estimated between £3,000 and £5,000.

Alongside application development, some internal and external contacts recommended Google Forms®, this is a tool on the Google Drive® which allows the creation of surveys and allows for the distribution of the survey using a URL (Figure 16.2). The survey is free to create and distribute and the responses from participants can be collated on to a spreadsheet which can then be exported into a number of file formats including into Microsoft Office Excel.

Upon collating the information gained from internal and external individuals it was decided that the Google Forms format would be the most suitable and feasible option for the time frame needed and costs. Google Forms allows for the survey to be accessed from online to those who have to URL to the live web survey (Figure 16.3 (a)), and also by smart phone, where the URL can be used by accessing the internet through browsers such as Google® or Safari®, or if the URL was sent by text users could click on the link and access a mobile
friendly version of the survey there if they have internet access (Figure 16.3 (b)). It was also considered that an assumption could not be made by the researcher that all participants would have access to a smartphone or online on a daily basis. Upon consideration of this, a paper version of the diary was also created.

![Breast Pain Diary](image)

**Figure 16.3:** Participants view of the breast pain diary in (a) online format (email) or (b) mobile format

The three available diary formats (online, mobile (using the online survey via a smartphone) and paper) were developed and were consistent in questions asked and format. Two questions were used to measure pain severity; intensity (0-10 numerical rating scale) (adapted from Hartrick, Kovan, & Shapiro, 2003), overall evaluation of pain (no pain, mild, discomforting, distressing, horrible or excruciating) (adapted from Maunsell, Allard, Dorval, & Labbé, 2000; Melzack, 1983).

Typically within cyclical breast pain the location of breast pain is in the upper outer quadrants of the breast (Cairncross, 2010). The purpose of a breast diary is to be able to understand the participants’ typical experience of breast pain and to monitor acute changes in pain post-treatment. The timing, frequency and severity of pain generate ordinal data which can show a directional change over a period of time (or following a treatment e.g. pain could get worse or better). The location of breast pain is not a scalable factor, therefore it is nominal data therefore would be less useful in a diary measure. These questions were from the breast pain section of the new Breast Pain Survey. An additional question asked participants whether they were currently menstruating. Two questions were added at the start of the diary to obtain the participants participant number and for participants to enter the date of diary completion. These two questions were needed as on Google Forms it does not identify respondents who complete the form, for the mechanical support intervention participants will be required to complete the diary daily over a number of months and it will
be important to be able to link up each participants daily results and to check their compliance with the diary.

16.2.2.3 Initial Survey: Participants
Following institutional ethical approval, 151 surveys were completed (Appendix F). Three responses were removed due to; not wishing to consent to participate (n = 1 and therefore not filling out the survey), a duplicate (n = 1) and a faked entry (n = 1), which left 148 useable surveys. Participants were required to experience regular breast pain (every month) and have experienced this pain for at least two months. Participants had to be aged 18 years and over to participate and premenopausal. Participants completed the survey online or by paper. Informed consent was obtained from all participants.

There are no bra size limitations to this study. This study involved no laboratory testing and, therefore, there was no fitness requirement for this study. Participants recruited for this study were asked if they would like to participate in the second part of the study; the daily diary and second survey (for the test-retest).

16.2.2.4 Diary: Participants
Following institutional ethical approval, twenty-one premenopausal female participants (age = 36 ± 9 years) consented to complete the breast pain diary (Appendix G) following the completion of the Breast Pain Survey. Twenty participants completed the diary in full; the two remaining participants were excluded from the analysis due to incomplete or no data being received.

16.2.2.5 Retest Survey: Participants
Nineteen of the participants who completed the breast pain diary and first Breast Pain Survey in full completed the second survey (Appendix H). The data from these participants were used to complete the test-retest reliability analysis.

16.2.2.6 Procedures
After completing the survey, participants who wished to take part in the second part of the study (diary and retest survey) decided the format they were to complete the diary in (paper (n = 6), email (n = 10) or mobile (n = 4)). Participants then completed the breast pain diary for 35 days. The 35 day duration was selected as the menstrual cycle could last between 21 and 35 days (Potten et al., 1988). It was important for this study that the full menstrual cycle was identified for the data to be assessed in both the validity and reliability aspects of the study. The diary was completed using an interval-contingent design (Bolger, Davis, & Rafaeli, 2003) as participants were required to report their breast pain daily prior to sleep regardless of whether they experienced pain that day. Participants were contacted weekly to check progress and on days the diary had not be completed. Once the 35 days were
completed, participants were asked to complete the Breast Pain Survey again containing an additional four questions to assess diary acceptability. These questions related to whether they found the diary was useful, clear, and easy to use and whether they liked the format. Participants were also given the opportunity to give feedback on the diary process itself qualitatively within this survey.

16.2.2.7 Data Analysis: Survey

Questions, which resulted in a numerical answer, were not coded and left in their original state for example, age. For the questions relating to the participants worst day of pain and the number of days of breast pain they experience per month if participants gave a range, for example “10 to 12 days” instead of “10 days” their answer was excluded from the analysis.

Categorical data (yes/no) questions were coded as yes = 1 and no = 2, the Present Pain Index (PPI) was coded mild = 1, discomforting = 2, distressing = 3, horrible = 4, excruciating = 5. The sensory descriptors for pain were coded based on the scaling determined within Melzack and Torgerson (1971). The coding for whether breast pain occurred in one or both breasts was; left breast = 1, right breast = 2 and both breasts = 3. The number of years of breast pain was coded; less than one year = 1, one to two years = 2, two to three years = 3, three to four years = 4, four to five years = 5, more than five years = 6. Bra size was not coded but split into the under band and cup sizes for analysis. The remaining questions within the survey resulted in open-ended answers and therefore no coding was completed.

The survey includes three main sections; demographics, typical breast pain experience and breast pain treatments (Table 16.1).
Table 16.1: Question and question number and the type of data analysis completed and presented within the results section of this study

<table>
<thead>
<tr>
<th>Question Number</th>
<th>Question</th>
<th>Analysis Presented</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NRS</td>
<td>Mode and Range</td>
</tr>
<tr>
<td>2 (a, b &amp; c)</td>
<td>Pain Pattern</td>
<td>% of ps who rated their breast pain to be within each category</td>
</tr>
<tr>
<td>3</td>
<td>PPI</td>
<td>Mode and Range</td>
</tr>
<tr>
<td>4</td>
<td>Number of days of breast pain</td>
<td>Mean and Standard Deviation (SD)</td>
</tr>
<tr>
<td>5</td>
<td>Worse breast pain day</td>
<td>Mode</td>
</tr>
<tr>
<td>6</td>
<td>Time of day that worst breast pain occurs</td>
<td>Inductive Content Analysis</td>
</tr>
<tr>
<td>7</td>
<td>Number of years of breast pain</td>
<td>Mode</td>
</tr>
<tr>
<td>8</td>
<td>Unilateral/Bilateral breast pain</td>
<td>Mode</td>
</tr>
<tr>
<td>9</td>
<td>Location of breast pain</td>
<td>% of participants who experienced breast pain in each quadrant and at the nipple of the breast</td>
</tr>
<tr>
<td>10 (a, b, c, d, e &amp; f)</td>
<td>Sensory descriptors of breast pain</td>
<td>Sensory score mean (%) of the maximum possible scale score</td>
</tr>
<tr>
<td>11</td>
<td>Treatments used for breast pain</td>
<td>% of participants who reported using each method for their breast pain</td>
</tr>
<tr>
<td>12 (a)</td>
<td>Side effects of treatments (yes/no)</td>
<td>% yes/no answers</td>
</tr>
<tr>
<td>12 (b)</td>
<td>Describe the side effects</td>
<td>Each reported side effect and corresponding number of participants who experienced it</td>
</tr>
<tr>
<td>12 (c)</td>
<td>Still using treatments for breast pain</td>
<td>% yes/no answers</td>
</tr>
<tr>
<td>13</td>
<td>What makes breast pain worse</td>
<td>Inductive Content Analysis</td>
</tr>
<tr>
<td>14</td>
<td>What makes breast pain more manageable</td>
<td>Inductive Content Analysis</td>
</tr>
<tr>
<td>15</td>
<td>Children (yes/no)</td>
<td>% yes/no answers</td>
</tr>
<tr>
<td>16</td>
<td>Number of children</td>
<td>Mode and Range</td>
</tr>
<tr>
<td>17</td>
<td>Whether children were breast-fed</td>
<td>% yes/no answers</td>
</tr>
<tr>
<td>18</td>
<td>Was breast pain experienced before having children</td>
<td>% yes/no answers</td>
</tr>
<tr>
<td>19</td>
<td>Using contraceptive (yes/no)</td>
<td>% yes/no answers</td>
</tr>
<tr>
<td>20</td>
<td>Type of contraceptive</td>
<td>Types of contraceptive grouped and % of participants who used this contraceptive</td>
</tr>
<tr>
<td>21</td>
<td>Date of last Menstruation</td>
<td>Whether participants were currently in their luteal or follicular phases of their menstrual cycle was calculated using the date of questionnaire completion and the number of days since their last menstruation. 0 to 14 days = Follicular, 14 to 35 days = Luteal, &gt; 35 days = not calculated.</td>
</tr>
<tr>
<td>22</td>
<td>Self-reported bra size</td>
<td>Mode and Range</td>
</tr>
<tr>
<td>23</td>
<td>Age</td>
<td>Mean and Standard Deviation (SD)</td>
</tr>
</tbody>
</table>

Data from questions 1, 3, 4, 5 and 7 were assessed for test-retest reliability. Data were input into IBM SPSS 22 for analysis. Descriptive statistics were initially completed and indicated the data were not normally distributed and that non-parametric statistics should be conducted. Wilcoxon signed rank tests were then conducted on the data to assess whether
the first survey data were significantly different ($P \leq 0.05$) to the second survey data. Intraclass correlations (ICC) (two way random for absolute agreement) were then completed on the data to assess the relationship between the data. Intraclass correlation coefficients of $> 0.9$ are considered strong, $0.8$ to $0.89$ moderate and between $0.7$ and $0.79$ the correlations are questionable (Currell & Jeukendrup, 2008).

16.2.2.8 Data Analysis: Diary

Data were input into Excel 2010 for coding. Overall pain was coded ‘0 = no pain’, ‘1 = mild’, ‘2 = discomforting’, ‘3 = distressing’, ‘4 = horrible’ and ‘5 = excruciating’, pain frequency was coded ‘0 = no pain’, ‘1 = only once’, ‘2 = every couple of hours’, ‘3 = every hour’ and ‘4 = all day’. Whether participants were on their menstrual cycle was coded as ‘1 = no’ and ‘2 = yes’.

Overall diary compliance was assessed by calculating the number of diary entries that should have been completed over the study ($n = 35$) for each participant and the number of those entries that were completed in the evening of each day. This value was calculated as a percentage of all the participants summed together. Participants who completed the diary entries in the morning of the succeeding day or at any other time were classed as non-compliant. Compliance was also assessed for the validity and reliability assessments.

Compliance was calculated in the same way and divided between the pre-menstrual and post-menstrual phases for each participant within the validity data compliance assessment. Within the test-retest data participants were asked to keep diary entries at least one hour apart, those who completed the retest diaries less than one hour apart or not on the same day as the test completion were deemed non-compliant. For participants who completed the diary using email or mobile phone a timestamp and date was present which allowed these entries to be assessed for compliance. Participants who completed the paper diaries could not be assessed for compliance so were used in all statistical tests.

To assess for validity the pre and post-menstrual stages were compared. These were six days prior to the onset of menstruation (days 23 to 28 of a 28 day menstrual cycle) and six days post-menstruation (days 5 to 10 of the menstrual cycle) (Freeman et al., 1996). These data were extracted from the whole diary set and scores were summed. Only compliant data and data from the paper diaries were used. Participants who experienced no pre-menstrual breast pain or had an unequal number of measured pre- or post-menstrual days of pain (due to missed days or non-compliance) were excluded from the validity analysis as this may skew the results. The remaining data were input into IBM SPSS Statistics 22 for statistical analysis. Descriptive statistics were conducted on the data to be used in validity tests and Shapiro-Wilks tests for normality indicated that the data were not normally
distributed. To assess the validity of the breast pain diary a non-parametric Wilcoxon signed rank test for matched pairs was completed; this compared the pre-menstruation to the post-menstruation scores for the group across the three measured variables (intensity, overall pain and frequency of pain). The alpha value was set to 0.05.

Diary reliability was assessed using the ICC analysis on test-retest data. Non-compliant data was also removed from the reliability analysis. ICC coefficients of > 0.9 are considered strong (Currell & Jeukendrup, 2008) and between 0.7 and 0.8 the correlations are questionable (Currell & Jeukendrup, 2008). Cronbach’s α test was run on the data collected on the test-retest days (only including the initial test data) to assess internal consistency of the answers presented by all participants across the whole diary. An α value of ≥ 0.9 has been used to assess reliability in previous studies (Locher, Goode, Roth, Worrell, & Burgio, 2001) however an α value of ≥ 0.7 is considered acceptable for internal consistency (Nunnally & Bernstein, 1994). DeVon et al. (2007) suggests that the criteria of ≥ 0.7 is appropriate for reliability if the purpose of the tool is research, however if the diary is to be used to make clinical treatment decisions then a value of ≥ 0.95 should be used.

Frequency analysis was conducted to assess acceptability of the diary based on the four areas assessed. Previous research has identified acceptability was between 61% and 83% for electronic diaries with a range of 33% and 67% for paper diaries (Palermo, Valenzuela, & Stork, 2004). With this information it is hoped that (as participants would have chosen their preferred diary method) that over 50% will accept the diary across all diary formats.

16.2.3 Initial Survey: Results

16.2.3.1 Demographics

The average age of participants completing the survey was 33 ± 10 years. The self-reported UK bra size distribution is shows a large range of size within the survey sample (Figure 16.4) (under band size missing/incorrect input = 4; cup size missing/incorrect = 10). Of these participants; 36% were of an AA to D bra cup size with the remaining participants (65%) a DD bra cup size or above.
Appendix E

Figure 16.4: Distribution of self-reported UK bra sizes for the participants who completed the Breast Pain Survey

Some form of contraceptive medication was used by 32% of participants and this was split by: contraceptive pill (62%), the coil (19%), the implant (15%), contraceptive injection (2%) and the Nuvaring (2%). Using the start date of the participants last menstruation and the date of the completion of the survey 39% of participants were in the Luteal phase of their menstrual cycle (>14 to <35 days since the start of their last menstruation), 39% were in the Follicular phase of their menstrual cycle (<14 days since the start of their last menstruation) and 22% of participants could not have their phase accurately calculated either due to missing data (n = 8), incorrect information (n = 13), their last menstruation was over 35 days ago (n = 9) or they were not currently experiencing a menstrual cycle (n = 3). Out of the 148 participants, 37% had had children (mode = 2, max = 4,) and of these 82% of participants had breast fed their children and 50% of participants had experienced breast pain before having children.

16.2.3.2 Typical Breast Pain Experience

Modal breast pain intensity was four out of 10 (range one to nine). Sixty-two percent of participants rated their breast pain as brief, momentary or transient, 74% rated their breast
pain as rhythmic, periodic or intermittent and 72% rated their breast pain to be continuous, steady or constant. Breast pain was discomforting to participants and on average participants experienced breast pain for $6 \pm 5$ days (mean $\pm$ SD) per month.

Day 27 was the most painful day (Figure 16.5). Within the figure it can be seen that the majority of participants experienced their most painful day of breast pain in the second half of the cycle which corresponds to the luteal phase (days 14 to 28).

![Figure 16.5](image)

**Figure 16.5:** Most painful day in the menstrual cycle for the participants within this study ($n = 128$).

Participant’s breast pain typically had been present for over five years was bilateral for the majority of participants. Breast pain was experienced in the morning by 20%, 11% afternoon, 42% evening, 16% night and 20% had no pattern or could not identify the time that their pain occurred. The outer two quadrants (upper and lower) of the breast where most of the participant’s breast pain was located (Figure 16.6).
Figure 16.6: Location of breast pain across the four quadrants of the breast and the nipple (n = 147, participants could report more than one area of the breast)

16.2.3.3 Breast Pain Treatments

Thirty-four of participants had never tried any treatments for their breast pain (Table 16.2). Out of the participants who had used at least one of the treatments described in Table 16.2, 8% had experienced some side effects. The side effects included; acid reflux (n = 1), mood swings (n = 1), nauseous (n = 1), hot sweats/flushes (n = 2), increased pain (n = 2). Of the participants who were using treatments 68.9% are still using the treatments they described.

Table 16.2: Percentage of participants who have used various treatments for their breast pain.

| Treatment                                                                 | % of participants who have used the treatment listed |
|________________________________________________________________________|_____________________________________________________|
| I have not tried any treatments                                           | 34.0                                                   |
| Pain Relief Medication (e.g. paracetamol)                                 | 32.7                                                   |
| Non-Steroidal Anti-Inflammatory Drugs (e.g. ibuprofen, diclofenac)       | 25.2                                                   |
| Changing Breast Support                                                   | 23.1                                                   |
| Gentle Massage                                                            | 19.7                                                   |
| Evening Primrose Oil                                                      | 19.0                                                   |
| Heat/Cold application                                                     | 17.0                                                   |
| Gentle Exercise                                                           | 17.0                                                   |
| Changing contraceptive medication                                         | 12.9                                                   |
| Altering diet and fluid intake                                           | 11.6                                                   |
| Relaxation Techniques                                                     | 6.8                                                    |
| Other                                                                     | 4.1                                                    |
| Tamoxifen                                                                | 0.7                                                    |
| Danazol                                                                  | 0                                                      |
| Bromocriptine                                                            | 0                                                      |
| Toremifene                                                               | 0                                                      |
| Ormeloxifene                                                             | 0                                                      |

Breast support and exercise/movement were the top two factors which made breast pain worse but are also the top two factors which make breast pain more manageable (Figure 16.7 and Figure 16.8).
**Appendix E**

Figure 16.7: Factors which make breast pain worse for the participants in this study (n=144)

<table>
<thead>
<tr>
<th>Category</th>
<th>Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Support (43)</td>
<td>Not Wearing a Bra/Bra Removal (12)</td>
</tr>
<tr>
<td></td>
<td>Poorly Fitted Bras (8)</td>
</tr>
<tr>
<td></td>
<td>Poor Support (8)</td>
</tr>
<tr>
<td></td>
<td>Tight Bras (5)</td>
</tr>
<tr>
<td></td>
<td>General Bra Wearing Causes Pain to be Worse (4)</td>
</tr>
<tr>
<td></td>
<td>Underwiring (2)</td>
</tr>
<tr>
<td></td>
<td>Wearing Bras for Extended Times (2)</td>
</tr>
<tr>
<td>Exercise/Movement (34)</td>
<td>General Exercise/Movement (17)</td>
</tr>
<tr>
<td></td>
<td>Running/Vigorous Exercise (9)</td>
</tr>
<tr>
<td></td>
<td>Not Exercising/Moving (6)</td>
</tr>
<tr>
<td></td>
<td>Sexual Activity (1)</td>
</tr>
<tr>
<td></td>
<td>Manual Work (1)</td>
</tr>
<tr>
<td>Hormonal-Related Factors (31)</td>
<td>Menstrual Cycle (18)</td>
</tr>
<tr>
<td></td>
<td>Hormones (6)</td>
</tr>
<tr>
<td></td>
<td>Contraceptives (4)</td>
</tr>
<tr>
<td></td>
<td>Pre-menstrual Symptoms (2)</td>
</tr>
<tr>
<td></td>
<td>Menopausal Status (1)</td>
</tr>
<tr>
<td>Contact/Pressure (25)</td>
<td>Touching/General Contact (12)</td>
</tr>
<tr>
<td></td>
<td>Laying on Breast (7)</td>
</tr>
<tr>
<td></td>
<td>Pressure to Breast (6)</td>
</tr>
<tr>
<td>Unsure/Nothing (25)</td>
<td>Unsure/Nothing (25)</td>
</tr>
<tr>
<td>Lifestyle Factors (13)</td>
<td>Stress (8)</td>
</tr>
<tr>
<td></td>
<td>Eating Habits (timing) (2)</td>
</tr>
<tr>
<td></td>
<td>Long Working Hours (1)</td>
</tr>
<tr>
<td></td>
<td>Bathing/Washing (1)</td>
</tr>
<tr>
<td></td>
<td>Tiredness (1)</td>
</tr>
<tr>
<td>Diet (8)</td>
<td>Poor Diet (8)</td>
</tr>
<tr>
<td></td>
<td>Fatty Foods (1)</td>
</tr>
<tr>
<td></td>
<td>Sugar (1)</td>
</tr>
<tr>
<td>Clothing (5)</td>
<td>Tight Clothing (4)</td>
</tr>
<tr>
<td></td>
<td>Fabrics (1)</td>
</tr>
<tr>
<td>Weather Conditions (5)</td>
<td>Cold Weather/Temperature (4)</td>
</tr>
<tr>
<td></td>
<td>Changes in Temperature (1)</td>
</tr>
<tr>
<td>Breast Size (4)</td>
<td>Having Large Breasts (2)</td>
</tr>
<tr>
<td></td>
<td>Heaviness of Breasts (1)</td>
</tr>
<tr>
<td></td>
<td>Size Changes with Menstruation (1)</td>
</tr>
<tr>
<td>Treatments (2)</td>
<td>Forgetting to use treatments (2)</td>
</tr>
<tr>
<td>Breast Temperature (1)</td>
<td>Heat of Breasts (1)</td>
</tr>
<tr>
<td>Other (1)</td>
<td>Other Health Conditions (1)</td>
</tr>
</tbody>
</table>
Figure 16.8: Factors which make breast pain more manageable for participants in this study (n = 146).
16.2.4 Diary: Results

16.2.4.1 Participants

Reported bra sizes ranged from 28 to 48, A to JJ. Thirty percent of participants (age: 35 ± 9 years) had given birth to at least one child (max = 2) and of these 83% had breast fed and 67% had experienced breast pain prior to having children. Forty-five percent of participants were currently taking some form of hormonal contraceptive medication. Participants on average rated their pain as five (mode) out of 10 and 13 out of 20 participants had experienced their pain for more than 5 years. Pain was bilateral in 19 participants and only nine participants had not tried any treatments for their breast pain.

16.2.4.2 Compliance

Overall compliance (daily compliance over the 35 days – all methods; paper, email and mobile) was 89% (Table 16.3). This was similar to the values for the compliance for the pre-menstrual phases and post-menstrual phases of the diary which were 89% and 88% respectively. Compliance to the test-retest days was lower with only 63% compliance for all participants completing the retest diary.

Table 16.3: Compliance rates (%) across the three breast pain diary formats

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Retest</th>
<th>Pre-menstrual phase</th>
<th>Post-menstrual phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper (n = 6)</td>
<td>98.6</td>
<td>76.7</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Email (n = 10)</td>
<td>84.7</td>
<td>52.7</td>
<td>84.8</td>
<td>78.8</td>
</tr>
<tr>
<td>Mobile (n = 4)</td>
<td>87.6</td>
<td>73.3</td>
<td>83.3</td>
<td>94.4</td>
</tr>
<tr>
<td>Mean (±SD): All Formats</td>
<td>90.3 (± 7.3)</td>
<td>67.6 (± 13.0)</td>
<td>89.4 (± 9.2)</td>
<td>91.1 (± 11.0)</td>
</tr>
<tr>
<td>Mean (±SD): Email/Mobile</td>
<td>86.2 (± 2.1)</td>
<td>63.0 (± 14.6)</td>
<td>84.1 (± 1.1)</td>
<td>86.6 (± 11.0)</td>
</tr>
</tbody>
</table>

16.2.4.3 Validity

Data for breast pain intensity (rated on a NRS, n=14) showed breast pain was significantly greater within the premenstrual phase (Σ (sum of pre-menstrual phase) = 189) compared to the post-menstrual phase (Σ (sum of post-menstrual phase) = 87) (Z = -2.453, P = 0.011). This pattern was seen in the overall PPI data (pre-menstrual Σ = 96, post-menstrual Σ = 41) (Z = -2.773, P = 0.003) and the frequency of breast pain (pre-menstrual Σ = 160, post-menstrual Σ = 86) (Z = -2.167, P = 0.028). These results showed that across the three measured areas of breast pain the pre-menstrual phase was deemed more painful than the post-menstrual phase.

16.2.4.4 Reliability

Table 16.4 shows the ICC’s for the data across the three measured areas of breast pain (intensity, overall evaluation and frequency). Internal consistency for the diary was α = 0.89.
Table 16.4: Mode responses for the breast pain diary with reliability statistics (n = 63).

<table>
<thead>
<tr>
<th></th>
<th>Mode</th>
<th>Range</th>
<th>ICC</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test</td>
<td>Min</td>
<td>Max</td>
<td></td>
</tr>
<tr>
<td>Intensity</td>
<td>0</td>
<td>9</td>
<td>0</td>
<td>0.96</td>
</tr>
<tr>
<td></td>
<td>Retest</td>
<td>0</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>PPI</td>
<td>Test</td>
<td>0</td>
<td>5 (Excruiting)</td>
<td>0 (No Pain)</td>
</tr>
<tr>
<td></td>
<td>Retest</td>
<td>0</td>
<td>4 (Horrible)</td>
<td>0 (No Pain)</td>
</tr>
<tr>
<td>Frequency</td>
<td>Test</td>
<td>0</td>
<td>4 (All Day)</td>
<td>0 (No Pain)</td>
</tr>
<tr>
<td></td>
<td>Retest</td>
<td>0</td>
<td>4 (All Day)</td>
<td>0 (No Pain)</td>
</tr>
</tbody>
</table>

* Denotes a significant ICC

16.2.4.5 Acceptability

All participants (n = 19) found the diary easy to use and found the questions asked were clear. When asked about whether participants liked the format of the diary 90% of participants (n = 17) said they did. Seventeen out of 19 participants also found keeping the diary useful, with one of the participants who stated they did not find keeping the diary useful said it was because they were aware of their breast pain already. Participants also had the option to give qualitative feedback on the diary with the feedback being that the diary was not complex enough for the pain experienced as some participants experienced multiple types of pain during the day and could not report both types. Another participant suggested that having the option to look over past diary days may help to assess pain. Two participants felt they were more aware of their pain as a result of completing the diary with one of these participants stating that they felt their pain was less now they have had time to consider the pain.

16.2.5 Retest Survey: Results

Wilcoxon signed rank tests only showed a significant ($P \leq 0.05$) difference in the pre (survey one) and post (survey two) responses to the NRS scale (Table 16.5). This initial analysis indicated that the other data from the remaining should not be significantly different in the second survey to the first survey completed. Intra class correlation statistics (Table 16.5) showed three significant ($P \leq 0.05$) relationships for the PPI, number of days of breast pain per month and the number of years breast pain was experienced. The relationships were weak for the PPI and Average number of days of pain and fell within the category of ‘questionable’ (ICC = 0.7 to 0.79) based on recommendations by Currrell and Jeukendrup (2008).
16.2.6 Discussion

The overall aim of this Chapter was to assess the reliability of a redeveloped Breast Pain Survey and to assess the validity and reliability of a new breast pain diary for measuring cyclical breast pain.

16.2.6.1 Diary

Overall compliance (for all three formats collectively) was 89% with similar values (> 84%) seen when each diary format was looked at individually. These values demonstrate higher compliance than a previous study (Palermo et al., 2004) (compliance was around 74%) which involved children completing pain diaries, but similar values to pain diaries completed by adult patients who were undergoing stem cell transplantation (Stiff et al., 2006).

Compliance was higher for participants who completed the paper diary compared to the other formats; caution must be taken for these values as the paper diary was not able to be monitored accurately for adherence or compliance. A previous study looking at the compliance between paper and electronic diaries showed that although participants reported compliance to be 91% the actual compliance was 11% and 80% of the compliance was faked (Stone, Shiffman, Schwartz, Broderick, & Hufford, 2003). A subsequent study (Broderick, Schwartz, Shiffman, Hufford, & Stone, 2003) which compared the results from Stone et al. (2003) to a group of participants who completed the same diary but were signalled to complete the diary found significantly higher compliance for the paper diaries however the authors deemed the improvement to be less than satisfactory as the improvements was from 11% to 29%. This suggests that the paper diary results from this study are lower than those reported.

Validity tests showed that the participants experienced a significantly (p < 0.05) higher level of breast pain within the premenstrual phase compared to the post menstrual phase across

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**Table 16.5: Test-retest reliability of the Breast Pain Survey**

<table>
<thead>
<tr>
<th></th>
<th>Wilcoxon</th>
<th>〈/〉</th>
<th>p</th>
<th>ICC</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS</td>
<td>-2.763</td>
<td>Post</td>
<td>0.004*</td>
<td>0.163</td>
<td>0.164</td>
</tr>
<tr>
<td>PPI</td>
<td>-1.897</td>
<td></td>
<td>0.109</td>
<td>0.636</td>
<td>0.001^</td>
</tr>
<tr>
<td>Number of days of breast pain</td>
<td>-0.590</td>
<td></td>
<td>0.583</td>
<td>0.452</td>
<td>0.035^</td>
</tr>
<tr>
<td>Worst day of breast pain</td>
<td>-0.551</td>
<td></td>
<td>0.620</td>
<td>0.158</td>
<td>0.267</td>
</tr>
<tr>
<td>Number of years of breast pain</td>
<td>-1.289</td>
<td></td>
<td>0.375</td>
<td>0.751</td>
<td>0.000^</td>
</tr>
</tbody>
</table>

* denotes significant difference
^ denotes significant correlation
the three questions (intensity, overall evaluation (PPI) and frequency) in the diary. This accepts hypotheses one. These were similar results to those found in the study by Freeman et al. (1996) who used a daily symptom record which identified that premenstrual symptom scores were higher in the premenstrual phase compared to the postmenstrual phase. These results are most likely similar as breast pain (or tenderness) is one of many symptoms of premenstrual syndrome (Freeman et al., 1996) and they have the same luteal phase pattern. Cyclical breast pain has been identified to occur during the luteal phase of the menstrual cycle (Ader & Shriver, 1997). The luteal phase (pre-menstruation phase) length is almost constant at 14 days per menstrual cycle with the variation in cycle lengths occurring due to the deviation in follicular phase (post-menstruation phase) lengths (Ramakrishnan, Khan, & Badve, 2002).

Reliability tests showed that the diary had an overall internal consistency value of $\alpha = 0.88$ which was high and related to previous research where internal consistency was 0.87 or greater (Freeman et al., 1996; Locher et al., 2001; Maunsell et al., 2000). Literature has identified that a Cronbach’s $\alpha \geq 0.7$ is considered acceptable for research, however a $\alpha \geq 0.9$ is considered a minimum if it is to be used as a clinical tool (DeVon et al., 2007). This indicates that the internal consistency is high enough to provide reliable research data however should not necessarily be used to make pivotal treatment decisions, this value is recommended to be $\geq 0.95$ (Tan, Jensen, Thornby, & Shanti, 2004). This has no implications for this thesis as the diary is being used as a monitoring tool not as a decision making tool. Further assessment of test-retest reliability showed strong ($r \geq 0.9$) (Vincent, 1995) correlations across all three questions on the test-retest days (Intensity; ICC = 0.96; Overall Evaluation (PPI); ICC = 0.92; Frequency; ICC = 0.93). This further indicates reliability and accepts hypotheses two. A previous diary study (Stiff et al., 2006) found test-retest correlations between 0.58 and 0.95 across the questions of the diary so the results found in this study are higher.

Another aim of the study was to assess whether participants found the diary an acceptable method of measuring their breast pain. The results showed that all participants found the diary easy to use and clear; this is positive as it showed participants were able to understand the questions being asked and it was a sufficient process for them. The majority of participants (90%) also found the diary was useful and liked the format of the diary they chose. These values were higher than the accepted values within another diary study (Palermo et al., 2004) and similar to the pain diaries completed by patients with cancer in the study by Maunsell et al. (2000).
One participant would have liked the opportunity to give more detail within the diary; this could be achieved by adding an additional box/space to the diary where participants could note any additional comments they may have. Another participant (mobile format) suggested that reviewing previous entries would help her to report each day of pain. Although this could be completed; the bias which may be attributed to the data could be higher as pain ratings are known to be moment specific (or transient) therefore recall is worse. This could mean participants perception of pain each day is greater influenced by the previous days diary (retrospective bias (Stone et al., 2003)) rather than an independent assessment each day. Interestingly, the Hawthorne effect (where observation or awareness may change perception or behaviour (Adair, 1984; De Amici, Klersy, Ramajoli, Brustia, & Politi, 2000)) may have influenced one participant who said the diary made her more aware of the breast pain she was experiencing, and made the pain felt less prominent. This shows that the act of completing the diary itself had an impact on pain perception and this should be considered within further Chapters of this thesis when the diary is implemented as a monitoring tool.

To conclude the new breast pain diary developed within this study is both valid and reliable for use within further breast health research studies and within this thesis as a monitoring tool. The diary is not however appropriate for use as a clinical decision tool. The compliance was high within electronic formats therefore these methods should be promoted over the use of paper diaries (as compliance cannot be monitored), however its acknowledged paper diaries may be the only option for some participants. The diary was easy to use, clear and useful for the majority of participants and with the addition of a comments space would provide participants with an opportunity to give further feedback.

16.2.6.2 Survey

The results showed a few questions were missed by participants and also there were a number of occasions where the questions were answered with answers that could not be used in the analysis stages. This suggested that the survey could be refined further in order to improve its functionality and the participant’s ability to understand the questions and the answers that would be required from them.

The Breast Pain Survey was found to be unreliable based on its current format (Table 16.1). It was a concern that there was a significant difference in the NRS scores provided in the pre and post survey completions. As no treatment was provided to these participants during the 35 day gap between the pre and post surveys a reliable response was expected. However, one participant suggested the mere act of completing the breast pain diary led to her re-evaluating her breast pain, and it could be suggested that this effect occurred for
more participants. Subsequently this may have caused the survey reliability to be questioned. It would be useful now the diary has been found to be reliable and valid to complete the test-retest again for the survey without the influence of the diary being present. If the survey is then found to be reliable, it could be suggested that the combination of the diary and the survey can influence the responses given by participants and potentially they should not be used in conjunction with each other.

To conclude, it is hypothesised that the reliability of the Breast Pain Survey may have been influenced by the breast pain diary and it should be assessed on its own. Due to a selection of missing and meaningless answers additional refinement to questions on the Breast Pain Survey can be added to maximise the amount of responses that can be included in future analyses.

16.3 Part B: Refinement of the Breast Pain Survey and further assessments of reliability

16.3.1 Aim

To reassess reliability using a same-day test-retest reliability method.

16.3.2 Methods

16.3.2.1 Refining the Breast Pain Survey

Appendix I shows the refined Breast Pain Survey. Some questions were removed from the survey (Questions six, 10 and 21) to speed up the completion process and to ensure only relevant and useful information was collected in the subsequent intervention study. Question six asked respondents at what time of day their pain occurred. The time of day of breast pain is not a scale type question and therefore would not provide relevant information on the effectiveness of a treatment for breast pain. Question ten was descriptors of breast pain, these descriptors were chosen as the original sample of the intervention study was going to be a cyclical breast pain cohort (and therefore pre-menopausal) however upon advice from the clinicians at the Queen Alexandra hospital, it was decided to expand the criteria to include post-menopausal women as well. The descriptors had been previously suggested in studies that they related to the typical breast pain described by cyclical breast pain sufferers (Khan & Apkarian, 2002a; Rosolowich et al., 2006). Adding in the descriptors also typically used by non-cyclical breast pain sufferers would add considerable length to the survey and would not add to the results, as the question was only being used for

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3 The explanation for the change in criteria will be described in the intervention chapter (chapter seven).
Appendix E

descriptive purposes so all descriptive terms were removed. Question 21 was also removed (when was your most recent or current period?) due to the inclusion of post-menopausal women, and also because the knowledge of this would not benefit the study itself.

Additional to the removal of questions one question was added to the survey, a question asking respondents to fill in what ethnic group they fall into. This question was taken from the Office for National Statistics Guidelines on asking questions about ethnic groups, specifically from the section relating to asking that question within a survey or survey (Office for National Statistics, n.d.). This question was added as it will allow for the assessment of the typical patient seen within a clinic population in Portsmouth along with the other demographic questions added. It may also provide another method to assess the effectiveness of the intervention, whether it was more/less effective for specific ethnicities.

The format of question two was altered to allow for only one pain pattern grouping to be picked. The previous format allowed for multiple groups to be selected which did not fall in line with the previous use of this type of question (Melzack, 2005). Additional explanations were added to questions asking; ‘how many days do you experience breast pain per month?’, ‘using the diagram above, on what day of the menstrual cycle is your breast pain worse?’ and ‘what is your current bra size’, this was to encourage participants to give one answer to represent their average number of days/worst day and the bra size they wear most often (e.g. 34D and not 34D/DD).

16.3.2.2 Procedures

Within Part A of this Chapter it was found that the Breast Pain Survey was not reliable after the diary was completed for 35 days between the test and retest surveys. The revised Breast Pain Survey therefore would be completed on the same day. This would allow for less fluctuation of breast pain as the day to day changes of breast pain could be substantial. This would also remove the diary aspect of the study so this could not provide any influence.

16.3.2.3 Data Analysis

The coding of the surveys and test for reliability (ICC) were completed using the same methods as section 16.2.2.7 of this Chapter.

16.3.3 Results

16.3.3.1 Demographics

Sixty-nine participants completed the test-retest survey online however one data set was removed due to inappropriate content and therefore consequently an incomplete entry. Sixty-eight responses were therefore used in the test-retest analysis for the survey.
Participants were aged 30 ± 10 years, had an average self-reported UK under band size of a 34 and a cup size of a C. Bra under band size ranged from 32 to 42 and cup sizes ranged from an A cup to a GG cup. Fifty-three percent of participants were an A to D cup size and 40% were a DD to GG cup. The remaining five participants did not complete their answers correctly meaning they could not be included in the modal data. Seventeen out of the 68 women (2%) who completed the survey had had children and of those the average number of children was 2. Seventy-one percent had breast fed their children and 24% had experienced breast pain before having children. Forty-six percent of participants were currently using some form of contraceptive medication.

Seventy-one percent of the participants stated they came from a “White - English/Welsh/Scottish/Northern Irish/British” background, 16% stated they fell into the “Any other White background”, 4% were of a Black/African/Caribbean/Black British – African background, 3% a Asian/Asian British – Indian background and 1% of the respondents fell into each of the “Any other Asian/Asian British background”, “Mixed/Multiple Ethnic Groups - White and Black African” “Mixed/Multiple Ethnic Groups - White and Black Caribbean” background” and “Any other Ethnic Group” background.

16.3.3.2 Survey Completion

As there were 24 questions in the refined survey, and 68 usable responses, there should have been a total of 1632 completed responses if all participants completed the questions appropriately or at all. In total there was only 1 (<1%) missing response in the refined survey compared to 16 (<1%) in the previous survey (Table 16.6). Thirty-two (2%) meaningless answers were given which is an equal percentage to the meaningless answers given in the previous survey (n = 93), despite greater instruction being given to the respondents in the questions.
Table 16.6: Missing and meaningless answers of the initial Breast Pain Survey compared to the refined Breast Pain Survey

<table>
<thead>
<tr>
<th>Question</th>
<th>Percentage of missing/meaningless answers</th>
<th>Refined BPQ</th>
<th>BPQ</th>
<th>Refined BPQ</th>
<th>BPQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pain Pattern A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pain Pattern B</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pain Pattern c</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PPI</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of Breast pain days per month</td>
<td>0</td>
<td>0</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Worst day in cycle</td>
<td>1</td>
<td>0</td>
<td>12</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Time of day</td>
<td>0</td>
<td>Removed from Questionnaire</td>
<td>2</td>
<td>Removed from Questionnaire</td>
<td>0</td>
</tr>
<tr>
<td>Number of years of breast pain</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bilateral vs Unilateral breast pain</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Location of breast pain</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Descriptors of Pain 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Descriptors of Pain 2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Descriptors of Pain 3</td>
<td>0</td>
<td>Removed from Questionnaire</td>
<td>0</td>
<td>Removed from Questionnaire</td>
<td>0</td>
</tr>
<tr>
<td>Descriptors of Pain 4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Descriptors of Pain 5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Descriptors of Pain 6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Treatments</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Side effects? Y/N</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>What were the side effects?</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Are you still using the treatments?</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>What makes breast pain worse?</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>What makes breast pain more manageable?</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Given birth?</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>How many children?</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Breastfed?</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Did breast pain occur before children?</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Contraceptives? Y/N</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>What contraceptives</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Start date of latest menstrual cycle</td>
<td>6</td>
<td>Removed from Questionnaire</td>
<td>7</td>
<td>Removed from Questionnaire</td>
<td>0</td>
</tr>
<tr>
<td>Bra size underband</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Bra size cups</td>
<td>3</td>
<td>0</td>
<td>4</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Age</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Added upon refining questionnaire</td>
<td>0</td>
<td>Added upon refining questionnaire</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

16.3.3.3 Test-Retest Reliability

All questions except whether pain was located bilaterally or unilaterally had a significantly strong correlation (>0.9) indicating reliability (Table 16.7). Whether breast pain was bilateral or unilateral had a moderate correlation (>0.8) for the ICC test based on recommendations
by Currell & Jeukendrup (2008). All questions had a significant correlation and ICC were much stronger than the test-retest completed previously.

Table 16.7: ICC statistics for the refined Breast Pain Survey

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>ICC</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS</td>
<td>68</td>
<td>0.945</td>
<td>&gt;0.01*</td>
</tr>
<tr>
<td>Pattern of breast pain</td>
<td>68</td>
<td>0.977</td>
<td>&gt;0.01*</td>
</tr>
<tr>
<td>PPI</td>
<td>68</td>
<td>0.973</td>
<td>&gt;0.01*</td>
</tr>
<tr>
<td>Number of days of breast pain per month</td>
<td>60</td>
<td>0.998</td>
<td>&gt;0.01*</td>
</tr>
<tr>
<td>Most painful day of menstrual cycle</td>
<td>61</td>
<td>0.998</td>
<td>&gt;0.01*</td>
</tr>
<tr>
<td>Number of years of breast pain</td>
<td>68</td>
<td>0.990</td>
<td>&gt;0.01*</td>
</tr>
<tr>
<td>Bilateral versus unilateral breast pain?</td>
<td>67</td>
<td>0.824</td>
<td>&gt;0.01*</td>
</tr>
</tbody>
</table>

* denotes significant correlation (p ≤ 0.05)

16.3.4 Discussion

The aim was to further refine the Breast Pain Survey and to test its test-retest reliability without the influence of the diary. Refining the survey led to no missing answers over the entirety of the survey except for one question which had one missing answer. This is an improvement compared to the initial survey completion. The number of meaningless answers was reduced for ten questions out of 14 in the previous Breast Pain Survey that had meaningless answers meaning that the survey had improved. A few adjustments can be made to improve this further however it is possible that there will always be occasions where questions are not completed as accurately as needed when a written response is required rather than a multiple choice, checkbox style question.

The reliability of the survey improved greatly, all questions that were assessed for test-retest reliability had significantly strong correlations (Currell & Jeukendrup, 2008) except for whether participants experienced breast pain in both or one of theirs breasts. This correlation although significant was only moderate in strength (0.8 to 0.89). This improvement suggests that the diary may have had an influence over the Breast Pain Survey itself or that the length of time between completions has been significantly reduced. If this is the case then it could be wise to not use the survey in conjunction with the diary unless the survey is used only once at the beginning of a study to get a more comprehensive view of breast pain. Once a participant is completing a breast pain diary, the survey should be used with caution as it would be difficult to confirm whether the diary or an intervention has caused a change in the survey responses.

In conclusion, the refined Breast Pain Survey and the Breast Pain Diary are both reliable and the breast pain diary is valid for use in patients with cyclical breast pain due to its pattern throughout the menstrual cycle. As the Survey and Diary may influence each other, only one should be used to assess the response of a treatment. The Breast Pain Survey could

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still be used alongside the Diary if it were used at the beginning of a study to understand the breast pain experience being had by participants.
17 **Appendix F: Initial Breast Pain Survey**

Breast Pain Survey 1

This study is part of a PhD project within the area of breast pain. The study requires you to complete three breast pain surveys and a breast pain diary over a period of one menstrual cycle. Your involvement in this study is very much appreciated and will help us understand cyclical breast pain and with the development of a breast pain treatment programme.

You are being asked to participate within this study as you fit the inclusion criteria detailed on the participant information sheet. Your participation in this study is voluntary and you may withdraw from this study at any time.

The raw data, which will identify you, will not be passed on to anyone outside the study team and will be kept securely by the principle investigator, Emma Burnett.

The data and results of this study, once made anonymous, may be published or presented at scientific meetings, within a PhD thesis, or as a scientific article. Anonymous data that does not identify you may be used in future research studies approved by an Appropriate Research Ethics Committee.

**Please confirm you have read the participant information sheet and agree to take part in this study (please initial)**
Participant Number: ___________

**Breast Pain**

*This section relates to your breast pain*

1. When you experience breast pain, what is the intensity (on AVERAGE)?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Worst Possible Pain</td>
</tr>
</tbody>
</table>

2. When you are suffering from breast pain, what is the PATTERN of your breast pain? Please tick one from each group. If no words within that group represent your pain tick none of the above.

**Group 1**
- Brief □
- Momentary □
- Transient □
- None of the above □

**Group 2**
- Rhythmic □
- Periodic □
- Intermittent □
- None of the above □

**Group 3**
- Continuous □
- Steady □
- Constant □
- None of the above □
3. How would you rate your breast pain OVERALL? Tick one.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>□</td>
</tr>
<tr>
<td>Discomforting</td>
<td>□</td>
</tr>
<tr>
<td>Distressing</td>
<td>□</td>
</tr>
<tr>
<td>Horrible</td>
<td>□</td>
</tr>
<tr>
<td>Excruciating</td>
<td>□</td>
</tr>
</tbody>
</table>

4. On AVERAGE, how many days do you experience breast pain per month?

_____________________________________________________________

5. Using the diagram above, on WHAT DAY of the menstrual cycle is your breast pain WORSE? Please write a number from 1 to 28 on the line below. The red arrows indicate the start of menstruation.

6. At what TIME of the day is your breast pain WORSE? Please answer fully, for example, you may find your pain is worse in the mornings.
7. How LONG have you experienced breast pain for?

- Less than 1 year □
- 1 to 2 years □
- 2 to 3 years □
- 3 to 4 years □
- 4 to 5 years □
- More than 5 years □

8. Do you experience breast pain in your:

- Left breast □
- Right breast □
- Both breasts □

9. Using the diagram above, please identify the AREA you typically feel BREAST PAIN. Please tick all that apply.

- 1 □
- 2 □
- 3 □
- 4 □
- Nipple □
Description of Pain

10. On this page there are six groups of words that DESCRIBE pain, from EACH GROUP please TICK ONE descriptor if it applies to you – if NO WORDS in that group relate to your pain tick NONE.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flickering</td>
<td>Sharp</td>
</tr>
<tr>
<td>Quivering</td>
<td>Cutting</td>
</tr>
<tr>
<td>Pulsing</td>
<td>Lacerating</td>
</tr>
<tr>
<td>Throbbing</td>
<td>None</td>
</tr>
<tr>
<td>Beating</td>
<td></td>
</tr>
<tr>
<td>Pounding</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th>Group 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dull</td>
<td>Tender</td>
</tr>
<tr>
<td>Sore</td>
<td>Taut</td>
</tr>
<tr>
<td>Hurting</td>
<td>Raspaging</td>
</tr>
<tr>
<td>Aching</td>
<td>Splitting</td>
</tr>
<tr>
<td>Heavy</td>
<td>None</td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 3</th>
<th>Group 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricking</td>
<td>Jumping</td>
</tr>
<tr>
<td>Boring</td>
<td>Flashing</td>
</tr>
<tr>
<td>Drilling</td>
<td>Shooting</td>
</tr>
<tr>
<td>Stabbing</td>
<td>None</td>
</tr>
<tr>
<td>Piercing</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
**Treatment of Breast Pain**

*This section relates to the treatment of your breast pain*

11. Have you ever USED or PARTICipated in any of the TREATMENTS below? *(Tick as many options as necessary, please use the ‘other’ category if your treatment is not listed)*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>☐</th>
<th>☐</th>
<th>☐</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamoxifen</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Danazol</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Bromocriptine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Danazol</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Toremifene</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ormeloxifene</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Bromocriptine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Tenderffield</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Evening Primrose Oil</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Relaxation techniques</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Changing breast support</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Changing contraceptive medication</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Pain relief medication e.g. paracetamol</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Non-steroidal Anti-Inflammatory drugs e.g. ibuprofen, diclofenac</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Heat/cold application</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Altering diet or fluid intake</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Gentle Exercise</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I have not tried any treatments</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other: Please describe</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

12a. Have you EXPERIENCED ANY SIDE EFFECTS of the treatment you have used?

- Yes ☐
- No ☐
- N/A ☐

12b. If yes, WHAT SIDE EFFECTS did you have? *(Please describe)*

12c. Are you currently STILL USING the treatments you described above?

- Yes ☐
- No ☐
- N/A ☐
13. What do you think makes your breast pain WORSE?

14. What do you think makes your breast pain MORE MANAGEABLE?

Demographics
15. Have you had any children?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>□</td>
</tr>
<tr>
<td>No</td>
<td>□</td>
</tr>
</tbody>
</table>

16. If yes how many?

17. Did you breast feed your children?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>□</td>
</tr>
<tr>
<td>No</td>
<td>□</td>
</tr>
<tr>
<td>I don't have any children</td>
<td>□</td>
</tr>
</tbody>
</table>

18. Did you experience breast pain before you had your children?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>□</td>
</tr>
<tr>
<td>No</td>
<td>□</td>
</tr>
<tr>
<td>I don't have any children</td>
<td>□</td>
</tr>
</tbody>
</table>

19. Do you use contraceptive medication?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>□</td>
</tr>
<tr>
<td>No</td>
<td>□</td>
</tr>
</tbody>
</table>

20. If yes, what type?

21. What is the start date of your most recent or current period?
22. What is your current bra size?

23. What is your age?

Thank you participating in this survey
If you are concerned about your breast pain, please contact your GP
Appendix G: Breast Pain Diary

This diary relates to your cyclical breast pain today. Please complete this survey as fully as possible.

Participant number: ___________ Date: ___________

1. What is the intensity of your breast pain (on AVERAGE) today?

2. How would you rate your breast pain OVERALL today?

   No Pain □
   Mild □
   Discomforting □
   Distressing □
   Horrible □
   Excruciating □

3. How FREQUENTLY did your breast pain occur today?

   No Pain □
   All day □
   Every hour □
   Every couple of hours □
   Only once □

4. Are you currently menstruating?

   Yes □
   No □

Thank you for participating

If you are concerned about your breast pain, please contact your GP
19 Appendix H: Retest Breast Pain Survey (plus diary evaluation questions)

Breast Pain Survey 2

This is the second breast pain survey for you to complete. This survey also includes questions evaluating the breast pain diary you have been completing over the past month.

Participant Number: ____________

Breast Pain

This section relates to your breast pain

1. When you experience breast pain, what is the intensity (on AVERAGE):

\[
\begin{array}{cccccccccc}
0 & 1 & 2 & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 10 \\
\hline
\text{No Pain} & & & & & & & & & & \\
\text{Worst Possible} & & & & & & & & & & \text{Pain}
\end{array}
\]

2. When you are suffering from breast pain, what is the PATTERN of your breast pain?
Please tick one from each group. If no words within that group represent your pain tick none of the above.

<table>
<thead>
<tr>
<th>Group 1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief</td>
<td>□</td>
</tr>
<tr>
<td>Momentary</td>
<td>□</td>
</tr>
<tr>
<td>Transient</td>
<td>□</td>
</tr>
<tr>
<td>None of the above</td>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhythmic</td>
<td>□</td>
</tr>
<tr>
<td>Periodic</td>
<td>□</td>
</tr>
<tr>
<td>Intermittent</td>
<td>□</td>
</tr>
<tr>
<td>None of the above</td>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous</td>
<td>□</td>
</tr>
<tr>
<td>Steady</td>
<td>□</td>
</tr>
<tr>
<td>Constant</td>
<td>□</td>
</tr>
<tr>
<td>None of the above</td>
<td>□</td>
</tr>
</tbody>
</table>
3. How would you rate your breast pain OVERALL? Tick one.

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td></td>
</tr>
<tr>
<td>Discomforting</td>
<td></td>
</tr>
<tr>
<td>Distressing</td>
<td></td>
</tr>
<tr>
<td>Horrible</td>
<td></td>
</tr>
<tr>
<td>Excruciating</td>
<td></td>
</tr>
</tbody>
</table>

4. On AVERAGE, how many days do you experience breast pain PER MONTH?

5. Using the diagram above, on WHAT DAY of the menstrual cycle is your breast pain WORSE? Please write a number from 1 to 28 on the line below. The red arrows indicate the start of menstruation.

6. At what TIME of the day is your breast pain WORSE? Please answer fully, for example, you may find your pain is worse in the mornings.
7. How LONG have you experienced breast pain for?

- Less than 1 year □
- 1 to 2 years □
- 2 to 3 years □
- 3 to 4 years □
- 4 to 5 years □
- More than 5 years □

8. Do you experience breast pain in your:

- Left breast □
- Right breast □
- Both breasts □

9. Using the diagram above, please identify the AREA you typically feel BREAST PAIN. Please tick all that apply.

- Nipple □
- 1 □
- 2 □
- 3 □
- 4 □
Description of Pain

10. On this page there is six groups of words that DESCRIBE pain, from EACH GROUP please TICK ONE descriptor if it applies to you – if NO WORDS in that group relate to your pain tick NONE.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flickering</td>
<td>Sharp</td>
</tr>
<tr>
<td>Quivering</td>
<td>Cutting</td>
</tr>
<tr>
<td>Pulsing</td>
<td>Lacerating</td>
</tr>
<tr>
<td>Throbbing</td>
<td>None</td>
</tr>
<tr>
<td>Beating</td>
<td></td>
</tr>
<tr>
<td>Pounding</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th>Group 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dull</td>
<td>Tender</td>
</tr>
<tr>
<td>Sore</td>
<td>Taut</td>
</tr>
<tr>
<td>Hurting</td>
<td>Raspine</td>
</tr>
<tr>
<td>Aching</td>
<td>Splitting</td>
</tr>
<tr>
<td>Heavy</td>
<td>None</td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 3</th>
<th>Group 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricking</td>
<td>Jumping</td>
</tr>
<tr>
<td>Boring</td>
<td>Flashing</td>
</tr>
<tr>
<td>Drilling</td>
<td>Shooting</td>
</tr>
<tr>
<td>Stabbing</td>
<td>None</td>
</tr>
<tr>
<td>Piercing</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
**Treatment of Breast Pain**

*This section relates to the treatment of your breast pain*

11. Have you ever USED or PARTICIPATED in any of the TREATMENTS below? *(Tick as many options as necessary, please use the ‘other’ category if your treatment is not listed)*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>□</th>
<th>□</th>
<th>□</th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamoxifen</td>
<td>□</td>
<td>Danazol</td>
<td>□</td>
<td>Bromocriptine</td>
</tr>
<tr>
<td>Toremifene</td>
<td>□</td>
<td>Ormeloxifene</td>
<td>□</td>
<td>Gentle Massage</td>
</tr>
<tr>
<td>Changing breast support</td>
<td>□</td>
<td>Evening Primrose Oil</td>
<td>□</td>
<td>Relaxation techniques</td>
</tr>
<tr>
<td>Changing contraceptive medication</td>
<td>□</td>
<td>Pain relief medication e.g. paracetamol</td>
<td>□</td>
<td>Non-steroidal Anti-Inflammatory drugs e.g. ibuprofen, diclofenac</td>
</tr>
<tr>
<td>Heat/cold application</td>
<td>□</td>
<td>Altering diet or fluid intake</td>
<td>□</td>
<td>Gentle Exercise</td>
</tr>
<tr>
<td>I have not tried any treatments</td>
<td>□</td>
<td>Other: Please Describe</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12a. Have you EXPERIENCED ANY SIDE EFFECTS of the treatment you have used?  

- Yes □
- No □
- N/A □

12b. If yes, WHAT SIDE EFFECTS did you have? *(Please describe)*

12c. Are you currently STILL USING the treatments you described above?  

- Yes □
- No □
- N/A □
13. What do you think makes your breast pain WORSE?

14. What do you think makes your breast pain MORE MANAGEABLE?

Demographics
15. Have you had any children?
   - Yes □
   - No □

16. If yes how many?

17. Did you breast feed your children?
   - Yes □
   - No □
   - I don’t have any children □

18. Did you experience breast pain before you had your children?
   - Yes □
   - No □
   - I don’t have any children □

19. Do you use contraceptive medication?
   - Yes □
   - No □

20. If yes, what type?
21. What is the start date of your most recent or current period?

22. What is your current bra size?

23. What is your age?

**Evaluation**

Below are a few questions on the breast pain diary that you have completed.

24. What DIARY FORMAT did you use?

<table>
<thead>
<tr>
<th>Format</th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td></td>
</tr>
<tr>
<td>Online</td>
<td></td>
</tr>
<tr>
<td>Mobile</td>
<td></td>
</tr>
</tbody>
</table>

25. Did you find keeping the DIARY USEFUL?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

26. Did you find the diary EASY TO USE?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

27. Did you LIKE THE FORMAT of the diary?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

28. Were the questions being asked CLEAR?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
29. Please use the space below if there is anything else you would like to comment about the diary

____________

Thank you participating in this survey
If you are concerned about your breast pain, please contact your GP.
20  Appendix I: Refined survey (detailed in section 16) and Baseline breast pain survey (used in chapter seven)

Participant Number: _____________ (THIS WILL BE COMPLETED FOR YOU AT A LATER STAGE PLEASE LEAVE BLANK)

Breast Pain Intensity

*This section relates to your breast pain*

1. When you experience breast pain, what is the intensity (on AVERAGE)?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Worst Possible Pain</td>
</tr>
</tbody>
</table>

Breast Pain Demographics

2. When you are suffering from breast pain, what is the PATTERN of your breast pain? Please tick ONE GROUP of words.

| Brief | □ |
| Momentary | □ |
| Transient | |
| Rhythmic | |
| Periodic | □ |
| Intermittent | |
| Continuous | |
| Steady | □ |
| Constant | |
3. How would you rate your breast pain OVERALL? Tick one.

- **Mild** □
- **Discomforting** □
- **Distressing** □
- **Horrible** □
- **Excruciating** □

4. On AVERAGE, how many days do you experience breast pain per month? (please give one number ONLY e.g. 5 **days** not 4 to 5 **days**)

5. Using the diagram above, on WHAT DAY of the menstrual cycle is your breast pain WORSE? Please write a number from 1 to 28 on the line below. The red arrows indicate the start of menstruation. Please write one number only e.g. day 27 not days 26 to 28.
6. How LONG have you experienced breast pain for?

<table>
<thead>
<tr>
<th>Duration</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 year</td>
<td>☐</td>
</tr>
<tr>
<td>1 to 2 years</td>
<td>☐</td>
</tr>
<tr>
<td>2 to 3 years</td>
<td>☐</td>
</tr>
<tr>
<td>3 to 4 years</td>
<td>☐</td>
</tr>
<tr>
<td>4 to 5 years</td>
<td>☐</td>
</tr>
<tr>
<td>More than 5 years</td>
<td>☐</td>
</tr>
</tbody>
</table>

7. Do you experience breast pain in your:

<table>
<thead>
<tr>
<th>Side</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left breast</td>
<td>☐</td>
</tr>
<tr>
<td>Right breast</td>
<td>☐</td>
</tr>
<tr>
<td>Both breasts</td>
<td>☐</td>
</tr>
</tbody>
</table>

8. Using the diagram above, please identify the AREA you typically feel BREAST PAIN. Please tick all that apply.

<table>
<thead>
<tr>
<th>Area</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>☐</td>
</tr>
<tr>
<td>2</td>
<td>☐</td>
</tr>
<tr>
<td>3</td>
<td>☐</td>
</tr>
<tr>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>Nipple</td>
<td>☐</td>
</tr>
</tbody>
</table>
Treatment of Breast Pain (section completed at the initial assessment only)

This section relates to the treatment of your breast pain

9. Have you ever USED or PARTICIPATED in any of the TREATMENTS below? *(Tick as many options as necessary, please use the ‘other’ category if your treatment is not listed)*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamoxifen</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Danazol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bromocriptine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toremifene</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ormeloxifene</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentlemen Massage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changing breast support</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evening Primrose Oil</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relaxation techniques</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changing contraceptive medication</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain relief medication e.g. paracetamol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-steroidal Anti-Inflammatory drugs e.g. ibuprofen, diclofenac</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heat/cold application</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Altering diet or fluid intake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentle Exercise</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have not tried any treatments</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: Please describe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>....................................................................................</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10a. Have you EXPERIENCED ANY SIDE EFFECTS of the treatment you have used?

Yes ☑
No ☐
N/A ☐

10b. If yes, WHAT SIDE EFFECTS did you have? *(Please describe)*

10c. Are you currently STILL USING the treatments you described above?

Yes ☑
No ☐
N/A ☐
Appendix I

11. What do you think makes your breast pain WORSE?

12. What do you think makes your breast pain MORE MANAGEABLE?

Demographics
13. Have you had any children?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

14. If yes how many?

15. Did you breast feed your children?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>I don’t have any children</td>
<td></td>
</tr>
</tbody>
</table>

16. Did you experience breast pain before you had your children?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>I don’t have any children</td>
<td></td>
</tr>
</tbody>
</table>

17. Do you use contraceptive medication?

<table>
<thead>
<tr>
<th></th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

18. If yes, what type?

19. What is your current bra size? Please give the bra size you wear most often.
20a. Have you had any surgery to the breasts?

Yes □
No □

20b. If yes, what surgery did you have?

21. What is your menopausal status? Please note if your last period was over twelve months ago you are post-menopausal)

Pre-menopausal □  Mid-menopausal □  Post-menopausal □

20. What is your ethnic group? (Please tick the corresponding box)

Choose one option that best describes your ethnic group or background

White

a. English/Welsh/Scottish/Northern Irish/British □
b. Irish □
c. Gypsy or Irish Traveller □
d. Any other White background, please describe □ __________________

Mixed/Multiple ethnic groups

e. White and Black Caribbean □
f. White and Black African □
g. White and Asian □
h. Any other Mixed/Multiple ethnic background, please describe □ __________________

Asian/Asian British

i. Indian □
j. Pakistani □
k. Bangladeshi □
l. Chinese □
m. Any other Asian background, please describe □ __________________

Black/ African/Caribbean/Black British

n. African □
o. Caribbean □
p. Any other Black/African/Caribbean background, please describe □

Other ethnic group

q. Arab □

r. Any other ethnic group, please describe □ ________________________

21. What is your age?

THE NEXT STAGE OF THE SURVEY RELATES TO YOUR QUALITY OF LIFE.

21  Appendix J: Breast Pain Survey; to be completed at four and eight weeks

Breast Pain Intensity
1. When you experience breast pain, what is the intensity (on AVERAGE)?

Overall Health Rating
2. Since the start of the study, my overall status is:

| 1 □ | Very much improved |
| 2 □ | Much improved      |
| 3 □ | Minimally improved |
| 4 □ | No change          |
| 5 □ | Minimally worse    |
| 6 □ | Much worse         |
| 7 □ | Very much worse    |

Treatment Questions
3. Were you asked to attend the University of Portsmouth any time after your assessment at the Queen Alexandra Hospital in Portsmouth?
Appendix I

4. Did you wear the bra that you were given?

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<tr>
<td>Yes</td>
<td>□</td>
<td>If yes, go to question 4</td>
</tr>
<tr>
<td>No</td>
<td>□</td>
<td>If no, go to question 6</td>
</tr>
</tbody>
</table>

4a. How often did you wear the bra?

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<tbody>
<tr>
<td>Everyday</td>
<td>□</td>
</tr>
<tr>
<td>At least a couple of times a week</td>
<td>□</td>
</tr>
<tr>
<td>Once a week</td>
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<tr>
<td>Every couple of weeks</td>
<td>□</td>
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<tr>
<td>Never</td>
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<tr>
<td>Other: (please specify):</td>
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4b. Did you buy any additional bras in the size you were fitted as over the past eight weeks?

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4c. Were they the same as the bra you were given?

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<tr>
<td>Yes</td>
<td>□</td>
<td>If yes go to question 6</td>
</tr>
<tr>
<td>No</td>
<td>□</td>
<td>If no go to question 4d</td>
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</table>

4d. If no, where did you purchase the bras from? Please also give a style number or name of the product if you can remember.

PLEASE SKIP TO QUESTION 9
5. Why did you not wear the bra that you were given?

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<thead>
<tr>
<th>Reason</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>I did not like the bra</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The bra was uncomfortable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I preferred my own bras</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am not sure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: (please specify):</td>
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</table>

5a. Did you continue to wear your old bras?

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<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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**PLEASE SKIP TO QUESTION 9**

6. After being recommended to get a good fitting bra did you have a professional bra fitting?

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<tr>
<th>Option</th>
<th>Yes</th>
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</table>

7. Where did you go for your bra fitting?

_______________________________________________________________________

_______________________________________________________________________

7a. Did your bra size change?

<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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</table>

7b. If yes, what did it change to? E.g. did it change from a 34 F to a 32 E?

_______________________________________________________________________

_______________________________________________________________________

7c. Did you purchase new bras after the bra fitting?

<table>
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<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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</table>
7d. Did you continue to wear your old bras?

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<th>□</th>
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<tbody>
<tr>
<td>Yes</td>
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<tr>
<td>No</td>
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PLEASE SKIP TO QUESTION 9

8. Why did you not go for a professional bra fitting?

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<tbody>
<tr>
<td>I did not have time</td>
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<tr>
<td>I have had a bad bra fitting experience before</td>
<td></td>
</tr>
<tr>
<td>I think my bras fit me well</td>
<td></td>
</tr>
<tr>
<td>I do not know where to go and get fitted</td>
<td></td>
</tr>
<tr>
<td>I cannot afford to get new bras</td>
<td></td>
</tr>
<tr>
<td>I am not sure</td>
<td></td>
</tr>
<tr>
<td>Other: (please specify):</td>
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</table>

9. Did you also use the topical ibuprofen recommended by the nurses at QA?

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<th>□</th>
<th>If yes go to question 9a</th>
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<td>Yes</td>
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<td></td>
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<tr>
<td>No</td>
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</tbody>
</table>
9a. If yes, how often did you use the ibuprofen?

<table>
<thead>
<tr>
<th>Frequency</th>
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<tbody>
<tr>
<td>Everyday</td>
<td>□</td>
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<td>At least a couple of times a week</td>
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<tr>
<td>Once a week</td>
<td>□</td>
</tr>
<tr>
<td>Every couple of weeks</td>
<td>□</td>
</tr>
<tr>
<td>Never</td>
<td>□</td>
</tr>
<tr>
<td>Other: (please specify):</td>
<td>□</td>
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</table>

9b. Where did you apply the ibuprofen? Please use the diagram and indicate in the boxes on what area of the breast the ibuprofen was applied (tick all boxes that apply).

PLEASE SKIP TO QUESTION 11.

10. If no, why not?
11. Have you referred to the breast cancer care leaflet on breast pain?

   Yes □
   No □

12a. Have you made any changes to your diet in the past month?

   Yes □
   No □

12b. If yes, what changes have you made?

   ______________________________________________________
   ______________________________________________________

13a. Have you increased or decreased the amount of exercise you have completed in the past month?

   Yes □
   No □

13b. If yes, what changes have you made?

   ______________________________________________________
   ______________________________________________________

14a. Have you started or stopped any treatments/medications for breast pain in the past month?

   Yes □
   No □

14b. If yes, what changes have you made?

   ______________________________________________________
   ______________________________________________________

15a. Have you started or stopped any treatments/medications for any other health conditions in the past month?

   Yes □
   No □
15b. If yes, what changes have you made?
__________________________________________________________________________
__________________________________________________________________________

16a. Have you changed the type of contraceptive medication you use in the past month?

<table>
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<tbody>
<tr>
<td>Yes</td>
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<tr>
<td>No</td>
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</tbody>
</table>

16b. If yes, what changes have you made?
__________________________________________________________________________
__________________________________________________________________________

**Thank you for participating**

If you are concerned about your breast pain, please contact your GP.
Appendix I

22 Appendix K: Post-Consultation: Bra Services Survey

The Research Group in Breast Health at the University of Portsmouth are conducting a survey in the clinic today to ask patients their opinion about bra fitting and bra services that could be provided. The survey is 2 sides of A4, you will not be asked for your name or contact information, so, if you complete this survey you will remain anonymous. By completing the survey you are agreeing to take part in this study and the information you give to be retained for any future research approved by a Research Ethics Committee.

1. What were the reasons either you or your GP suggested for referral to the breast clinic today? For example, you experience breast pain or have found a lump.

2. Do you experience breast pain?
   Yes □
   No □
   If yes, when you experience breast pain, what is the intensity (on AVERAGE)? Please place an X on a number.

3. Do you currently wear a bra?
   Yes □ If yes, please go to question 5
   No □ If no, please go to question 4
   Other □ Please describe:
   ........................................................
   ........................................................
   (please go to question 4)

4. Do you plan to start wearing bras in the future?
   Yes □ If yes, please go to question 9
   No □ If no, please go to question 13

5. What is your current bra size?

6. Do you always wear well-fitting and supportive bra?
   Yes □
   No □

7. Are there any problems with the bras you wear? If yes, please describe
   Yes □
   No □

8. Would you be interested in getting help finding a well-fitting and supportive bra?
   Yes □
   No □
The University of Portsmouth are looking into developing a bra prescription service for women. A bra prescription service would require you to attend a session at the University where you would be fitted in a range of bras, which you would try out during various activities. The researchers at the University can then compare these new bras to your current bra to see if an improvement can be made. This service would tell you the best bra for you as well as some advice about bra fitting and breast health.

9. Would you be interested in taking up this type of service?
   ![Yes or No options]

10. Would you be willing to pay for this service?
    ![Yes or No options]

If yes, how much would you be willing to pay?

11. What would stop you from using this service? Please tick all that apply.

   a. I do not feel I need a new bra
   ![Yes or No options]

   b. I fit in the bras I currently wear
   ![Yes or No options]

   c. I would find it difficult to find time to attend this service
   ![Yes or No options]

   d. I am not worried enough about my bras to take this service up
   ![Yes or No options]

   e. I could not afford to get new bras
   ![Yes or No options]

   f. I do not want to be told what bra to wear
   ![Yes or No options]

   g. I would not want to attend the University of Portsmouth for this service
   ![Yes or No options]

   h. I do not get bra fittings usually
   ![Yes or No options]

   i. I do not wear bras
   ![Yes or No options]

   j. I do not think this will help me
   ![Yes or No options]

   k. I do not think a bra will help my breast condition
   ![Yes or No options]

   l. I am not interested in this service
   ![Yes or No options]

Please list any other reasons which may stop you from using this service:

________________________________________________________________________
________________________________________________________________________
12. What advice would you want to receive about bras or breast health? Please tick all that apply.

<table>
<thead>
<tr>
<th>a. Bra fitting</th>
<th>□</th>
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<tbody>
<tr>
<td>b. What bra styles to wear</td>
<td>□</td>
</tr>
<tr>
<td>c. What bras are supportive</td>
<td>□</td>
</tr>
<tr>
<td>d. Where to find bras</td>
<td>□</td>
</tr>
<tr>
<td>e. What I should not be wearing</td>
<td>□</td>
</tr>
<tr>
<td>f. Breast anatomy</td>
<td>□</td>
</tr>
<tr>
<td>g. What happens to the breast when I move</td>
<td>□</td>
</tr>
<tr>
<td>h. What happens to the breast as I age</td>
<td>□</td>
</tr>
<tr>
<td>i. What are the problems with wearing poorly fitting bras</td>
<td>□</td>
</tr>
<tr>
<td>j. How to find a good sports bra</td>
<td>□</td>
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</tbody>
</table>

Please list any other advice you might like to receive:

______________________________

______________________________

A bit about you:

13. What is your age?

______________________________

14. Have you had surgery to the breasts?

Yes □

No □

If yes, what surgery have you had?

______________________________

______________________________

15. What is your menopausal status? Please note if your last period was over 12 months ago you are post-menopausal.

Post-menopausal □

Peri-menopausal □

Post-menopausal □

Thank you for completing this survey.

Please leave the survey in the box in reception or hand it to a member of staff
Appendix L: Non-clinical cohort survey

The Research Group in Breast Health at the University of Portsmouth are conducting a survey to ask your opinion about bra fitting and bra services that could be provided. The University of Portsmouth are looking to develop a bra prescription service for women. We are conducting this survey to understand who is interested in this service and also to identify any barriers to taking up this service. You must be female, aged 18 years and over and live in the UK to complete the survey.

You will not be asked for your name or contact information, so, if you complete this survey you will remain anonymous. By completing the survey you are agreeing to take part in this study and the information you give to be retained for any future research approved by a Research Ethics Committee. You may stop completing the survey at any time.

If you have any questions about the study please email emma.sharland@port.ac.uk

If your concern or complaint is not resolved by the researcher or their supervisor, you should contact the Head of Department:

Dr Richard Thelwell
Department of Sport and Exercise Sciences
University of Portsmouth
Spinnaker Building
Cambridge Road
Portsmouth
PO1 2ER
02392845164

If the complaint remains unresolved, please contact:
The University Complaints Officer
02392843642

1. Do you live in the UK?
   Mark only one oval
   O   Yes
   O   No       Stop filling out this form.

2. Have you lived in the UK since birth?
   Mark only one oval.
   O   Yes      Skip to question 4.
   O   No
3. How long have you lived in the UK?

A bit about you
The first few questions are about you, your physical activity levels and some breast related factors. After this section you will be asked whether you experience breast pain, any bra wearing habits and then about the bra services we could offer.

4. What is your age?

5. What is your postcode? Please leave the first four letters/numbers only.

   This will not be used to identify you. This will be used to identify the rough area you live in and how close this is to Portsmouth.

6. Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like running or football for at least 10 minutes continuously?

   Mark only one oval.
   - Yes   Skip to question 7.
   - No   Skip to question 9.

7. How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?

   Example: 4.03.32 (4 hours, 3 minutes, 32 seconds)

8. In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational leisure activities?

9. Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking, cycling, swimming, volleyball for at least 10 minutes continuously?

   Mark only one oval.
   - Yes   Skip to question 10.
   - No   Skip to question 12.

10. How much time do you spend doing moderate-intensity sports, fitness or recreational activities on a typical day?

    Example: 4.03.32 (4 hours, 3 minutes, 32 seconds)
11. In a typical week, on how many days do you do moderate-intensity sports, fitness or reactional leisure activities?

12. Have you had any surgery to the breasts?
   - O Yes
   - O No

13. If yes, what surgery have you had?

14. Please tick the category that applies most to you
   *Mark only one oval.*
   - O I am pregnant  
     Skip to question 15.
   - O I am breastfeeding  
     Skip to question 19.
   - O I am recovering from breast cancer  
     Skip to question 24.
   - O None of these categories apply to me  
     Skip to question 30.

**Breast Pain and Pregnancy**

15. Do you experience breast pain?
   *Mark only one oval.*
   - O Yes  
     Skip to question 16.
   - O No  
     Skip to question 32.

16. When you experience breast pain, what is the intensity (on AVERAGE)? Please tick a number.
   *Mark only one oval.*

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<td>9</td>
<td>10</td>
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</table>

   | No Pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Worst Possible Pain |

17. Did you experience breast pain prior to becoming pregnant?
   *Mark only one oval.*
   - O Yes
   - O No  
     Skip to question 32.

18. Do you think your breast pain is related to your pregnancy?
   - O Yes  
     Skip to question 32.
   - O No  
     Skip to question 32.

**Breast Pain and Breastfeeding**

19. Do you experience breast pain?
   *Mark only one oval.*
   - O Yes  
     Skip to question 20.
   - O No  
     Skip to question 32.

20. When you experience breast pain, what is the intensity (on AVERAGE)? Please tick a number.
   *Mark only one oval.*

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</table>

   | No Pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Worst Possible Pain |

21. Do you think your breast pain is related to breastfeeding?
   *Mark only one oval.*
   - O Yes
   - O No
22. Did you experience breast pain during your pregnancy?
   *Mark only one oval.*
   O Yes
   O No

23. Did you experience breast pain prior to becoming pregnant?
   *Mark only one oval.*
   O Yes  *Skip to question 32.*
   O No  *Skip to question 32.*

**Breast pain and Breast Cancer**

24. Do you experience breast pain?
   O Yes  *Skip to question 25.*
   O No  *Skip to question 27.*

25. When you experience breast pain, what is the intensity (on AVERAGE)?
   Please tick a number.
   *Mark only one oval.*

26. Did you experience breast pain prior to becoming diagnosed with breast cancer?
   *Mark only one oval.*
   O Yes  *Skip to question 27*
   O No  *Skip to question 27*

**Treatment**

27. During your treatment for breast cancer did you have any of the following surgeries?
   *Mark only one oval.*
   O Unilateral mastectomy
   O Bilateral mastectomy
   O Wide Local Excision
   O (WLE)/Lumpectomy
   O Wide Local Excision (WLE)/Lumpectomy and Radiotherapy
   O None

28. Did you have immediate breast reconstruction?
   *Mark only one oval.*
   O Yes
   O No

29. If yes, what reconstruction did you have?
   *Mark only one oval.*
   O Breast Implant  *Skip to question 32*
   O Back  *Skip to question 32*
   O Latissimus Dorsi (LD) flap  *Skip to question 32*
   O Tummy TRAM flap  *Skip to question 32*
   O Tummy DIEP or SIEA flap  *Skip to question 32*
Breast Pain
30. Do you experience breast pain?

*Mark only one oval.*

- O Yes
- O No

31. If yes, when you experience breast pain, what is the intensity (on AVERAGE)? Please tick a number.

*Mark only one oval.*

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No Pain 0 0 0 0 0 0 0 0 0 0 Worst Possible Pain

Bra Wearing
32. Do you currently wear a bra?

*Mark only one oval.*

- O Yes  
  *Skip to question 34.*
- O No  
  *Skip to question 33.*
- O Other: __________________________________
  
  *Skip to question 34.*

Future Bra Use
33. Do you plan to start wearing bras in the future?

*Mark only one oval.*

- O Yes
- O No  
  *Stop filling out this form*

Bra Sizing
34. What is your current bra size?


35. What type of bra do you wear on a daily basis?

*Tick all that apply.*

- O Balconette
- O Plunge
- O Demi-cup
- O Full-cup
- O Sports
- O Maternity
- O Nursing
- O Post-surgery
- O T-shirt
- O Minimiser
- O Strapless
- O Padded
- O Non-padded
- O Underwired
- O Non-wired
- O Other: ____________________________

36. Do you always wear well-fitting and supportive bras?

*Mark only one oval.*

- O Yes
- O No
37. Are there any problems with the bras you wear?
Mark only one oval.
O Yes
O No

38. If yes, please describe

39. Would you be interested in getting help finding a well-fitting and supportive bra?
Mark only one oval.
O Yes
O No

Bra Services
The University of Portsmouth are looking into developing a bra prescription service for women. A bra prescription service would require you to attend a session at the University where you would be fitted in a range of bras, which you would try out during various activities. The researchers at the University can then compare these new bras to your current bra to see if an improvement can be made. This service would tell you the best bra for you as well as some advice about bra fitting and breast health.

40. Would you be interested in taking up this type of service?
Mark only one oval.

41. Would you take up this type of service?
O Yes Skip to question 42.
O No Skip to question 44.

42. Would you be willing to pay for this service?
Mark only one oval.
O Yes
O No

43. If yes, how much would you be willing to pay?

Barriers to using this service
44. What would stop you from using this service?
Tick all that apply.
O a. I do not feel I need a new bra
O b. I fit in the bras I currently wear
O c. I would find it difficult to find time to attend this service
O d. I am not worried enough about my bras to take this service up
45. Please list any other reasons which may stop you from using this service.

46. What advice would you want to receive about bras or breast health? Please tick all that apply.

   Tick all that apply.
   O  a. Bra fitting
   O  b. What bra styles to wear
   O  c. What bras are supportive
   O  d. Where to find bras
   O  e. What I should not be wearing
   O  f. Breast anatomy

   O  g. What happens to the breast when I move
   O  h. What happens to the breast as I age
   O  i. What are the problems with wearing poorly fitting bras
   O  j. How to find a good sports bra

47. Please list any other advice you might like to receive

________________________________________________________________________

________________________________________________________________________

Thank you for completing this survey.

Please return this survey in the prepaid envelope provided.

The Research Group in Breast Health
24 Ethics Documents

Science Faculty Ethics Committee
Department of Sport & Exercise Science
University of Portsmouth
Spinnaker Building
Cambridge Road
PORTSMOUTH
PO1 2ER

Emma Burnett
Department of Sport & Exercise Science
University of Portsmouth
Spinnaker Building
Cambridge Road
PORTSMOUTH
PO1 2ER

T: 023 9284 5145
F: 023 9284 3620
jim.house@sport.ac.uk

31 July 2014

PROTOCOL AMENDMENT - FAVOURABLE OPINION – SFEC 2014-034a

Protocol Title: Cyclical Breast Pain Focus Group and Individual Interviews; Bra Problems
Date Submitted: 24 July 2014
Date Reviewed: 24 July 2014

Thank you for submitting your protocol amendment to the Science Faculty Ethics Committee (SFEC) for ethical review in accordance with current procedures¹. I am pleased to inform you that following review, your application has been given a favourable opinion by the Science Faculty Ethics Committee (SFEC).

This is formal notification of the informal email favourable opinion forwarded on 25 July 2014.

Please notify us in the future of any substantial amendments that may be required.

Please also submit a final study report / publication in due course.

Good luck with the study.

Dr Jim House
Vice-Chair Science Faculty Ethics Committee

Information:
Dr Chris Markham - Chair Science Faculty Ethics Committee
Holly Shawyer - Faculty Administrator
Professor Jo Scurr - 1st Supervisor

¹ Procedures for Ethical Review, Science Faculty Ethics Committee, University of Portsmouth, October 2012.
28 August 2015

Professor Joanna Scurr
University of Portsmouth, Department of Sport and Exercise Science
Spinnaker Building, Cambridge Road
Portsmouth
PO1 2ER

Dear Professor Scurr,

<table>
<thead>
<tr>
<th>Study title:</th>
<th>A randomised control trial of an individual bra prescription versus standard care for women with larger breasts and breast pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>REC reference:</td>
<td>15/EM/0386</td>
</tr>
<tr>
<td>Protocol number:</td>
<td>1</td>
</tr>
<tr>
<td>IRAS project ID:</td>
<td>182133</td>
</tr>
</tbody>
</table>

Thank you for your letter of August 20th 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 12 August 2015.

Documents received

The documents received were as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other [Sponsor Information]</td>
<td>1</td>
<td>05 August 2015</td>
</tr>
<tr>
<td>Other [Response Letter]</td>
<td>1</td>
<td>20 August 2015</td>
</tr>
<tr>
<td>Other [Protocol ]</td>
<td>2</td>
<td>20 August 2015</td>
</tr>
<tr>
<td>Other [Participant Information Sheet]</td>
<td>2</td>
<td>20 August 2015</td>
</tr>
</tbody>
</table>

Approved documents

The final list of approved documentation for the study is therefore as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copies of advertisement materials for research participants [Study Advertisement]</td>
<td>1</td>
<td>23 July 2015</td>
</tr>
<tr>
<td>Evidence of Sponsor insurance or indemnity (non NHS Sponsors)</td>
<td>1</td>
<td>28 July 2015</td>
</tr>
<tr>
<td>Document Description</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>Evidence of Sponsor Insurance or Indemnity (non NHS Sponsors only) [Employers' liability insurance 2015]</td>
<td>01 August 2015</td>
<td></td>
</tr>
<tr>
<td>IRAS Checklist XML [Checklist_05082015]</td>
<td>05 August 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Best Fit Criteria]</td>
<td>23 July 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Additional information missing from REC Application form QA64-1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other [Exercise and Health History Questionnaire]</td>
<td>05 July 2014</td>
<td></td>
</tr>
<tr>
<td>Other [Four and Eight Week Breast Pain Questionnaire]</td>
<td>23 July 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Participant Contact Sheet]</td>
<td>23 July 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Subjective Measures]</td>
<td>23 July 2015</td>
<td></td>
</tr>
<tr>
<td>Other [VAS Instructions]</td>
<td>23 July 2015</td>
<td></td>
</tr>
<tr>
<td>Other [PARTICIPANT CHASING EMAIL/TELEPHONE CALL]</td>
<td>06 August 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Sponsor Information]</td>
<td>06 August 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Response Letter]</td>
<td>20 August 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Protocol ]</td>
<td>20 August 2015</td>
<td></td>
</tr>
<tr>
<td>Other [Participant Information Sheet]</td>
<td>20 August 2015</td>
<td></td>
</tr>
<tr>
<td>Participant consent form [Consent Form]</td>
<td>28 July 2015</td>
<td></td>
</tr>
<tr>
<td>REC Application Form [REC_Form_04082015]</td>
<td>04 August 2015</td>
<td></td>
</tr>
<tr>
<td>Summary CV for Chief Investigator (CI) [Joanna Scurr CV]</td>
<td>26 July 2015</td>
<td></td>
</tr>
<tr>
<td>Summary CV for student [Emma Burnett CV]</td>
<td>28 July 2015</td>
<td></td>
</tr>
<tr>
<td>Summary CV for supervisor (student research) [Jonny Burbago CV]</td>
<td>28 July 2015</td>
<td></td>
</tr>
<tr>
<td>Validated questionnaire [SF36]</td>
<td>23 July 2015</td>
<td></td>
</tr>
</tbody>
</table>

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor’s responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/EM/0386  Please quote this number on all correspondence

Yours sincerely,

Rachel Nelson
REC Manager

E-mail: NRESCommittee.EastMidlands-Nottingham1@nhs.net

Copy to: Miss Emma Burnett
11 November 2015

Mr David Carpenter
School of Social, Historical and Literary Studies, Milldam,
Burnaby Road, Portsmouth, Hants
PO1 3AS

Dear Mr Carpenter,

Study title: A randomised control trial of an individual bra prescription versus standard care for women with larger breasts and breast pain

REC reference: 15/EM/0386
Protocol number: 1
Amendment number: Substantial Amendment 1 28.10.2015
Amendment date: 29 October 2015
IRAS project ID: 182133

The above amendment was reviewed at the meeting of the Sub-Committee held on 10 November 2015.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee reviewed the Substantial Amendment for the above study and had the following query:

1. There is only a free text box to describe what surgery the participant has had in the past. The participant may not know the exact procedure, are you happy to proceed this way? The Sub-Committee noted that a drop down menu may work for more accurate responses and questioned the reasoning behind the free text box?

The Applicant responded as follows:

Having spoken to the breast care clinicians at the Queen Alexandra Hospital in Portsmouth about this query, they and I feel that leaving the question open for participants to complete is the best option. The types of surgery are very varied and having a drop down menu may generate a long list. Patients are likely to know the basic procedure they may have had done (e.g. breast implants, reduction surgery, lump removal, cyst drainage), even if they do...
not know the technical names and I am happy to proceed with the study knowing this information alone.

The Sub-Committee Chair approved the response.

**Approved documents**

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copies of advertisement materials for research participants</td>
<td>2</td>
<td>28 October 2015</td>
</tr>
<tr>
<td>Non-validated questionnaire</td>
<td>2</td>
<td>28 October 2015</td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMP)</td>
<td>Substantial Amendment 1 28 10 2015</td>
<td>29 October 2015</td>
</tr>
<tr>
<td>Participant Information sheet (PIS)</td>
<td>3</td>
<td>28 October 2015</td>
</tr>
<tr>
<td>Research protocol or project proposal</td>
<td>3</td>
<td>28 October 2015</td>
</tr>
</tbody>
</table>

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at [http://www.hra.nhs.uk/hra-training/](http://www.hra.nhs.uk/hra-training/)

15/EM/0386: Please quote this number on all correspondence

Yours sincerely

[Signature]

Dr Carl Edwards  
Chair

E-mail: NRESCommittee.EastMidlands-Nottingham1@nhs.net

**Enclosures:** List of names and professions of members who took part in the review
20 April 2016

Professor Joanna Scurr
University of Portsmouth, Department of Sport and Exercise Science
Spinnaker Building, Cambridge Road
Portsmouth
PO1 2ER

Dear Professor Scurr

<table>
<thead>
<tr>
<th>Study title:</th>
<th>A randomised control trial of an individual bra prescription versus standard care for women with larger breasts and breast pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>REC reference:</td>
<td>15/EM/0385</td>
</tr>
<tr>
<td>Protocol number:</td>
<td>1</td>
</tr>
<tr>
<td>Amendment number:</td>
<td>Substantial Amendment 2 7th April 2016</td>
</tr>
<tr>
<td>Amendment date:</td>
<td>07 April 2016</td>
</tr>
<tr>
<td>IRAS project ID:</td>
<td>162133</td>
</tr>
</tbody>
</table>

The above amendment was reviewed on 19 April 2016 by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covering letter on headed paper</td>
<td></td>
<td>07 April 2016</td>
</tr>
<tr>
<td>Non-validated questionnaire [Health and Well-Being Questionnaire]</td>
<td>1</td>
<td>07 April 2016</td>
</tr>
<tr>
<td>Non-validated questionnaire [Post Consultation Questionnaire]</td>
<td>1</td>
<td>07 April 2016</td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMP) [Addition of Questionnaire]</td>
<td>Substantial Amendment 2 7th April 2016</td>
<td>07 April 2016</td>
</tr>
<tr>
<td>Research protocol or project proposal</td>
<td>4</td>
<td>07 April 2016</td>
</tr>
</tbody>
</table>
Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

| 15/EM/0386: Please quote this number on all correspondence |

Yours sincerely

[Signature]

Professor Cris Constantinescu
Alternate Vice Chair

E-mail: NRESCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Mr Graham Halls, Portsmouth Hospitals Trust
         Mr David Carpenter
FAVOURABLE ETHICAL OPINION – NOTIFICATION OF SUBSTANTIAL AMENDMENT

Study Title: A questionnaire study to assess the interest in a bra prescription service in UK women.

Reference Number: SFEC 2017-011A

Date Submitted: 17 February 2017

Thank you for submitting your proposal amendment to the Science Faculty Ethics Committee (SEFC) for ethical review in accordance with current procedures.

I am pleased to inform you that SFEC was content to grant a favourable ethical opinion of this proposal amendment on the basis described in the submitted documents listed at Annex A, and subject to standard general conditions (See Annex B)., and the following specific minor condition(s).

Condition(s)¹

A. Please ask for only the first four letters/numbers in the post code to ensure anonymity.

Please resubmit an updated application form incorporating the changes as per the above conditions for the final SFEC records on this application.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact ethics-sci@port.ac.uk who will circulate your queries to SFEC.

Please note that the favourable opinion of SFEC does not grant permission or approval to undertake the research. Management permission or approval must be obtained from any

¹ The favourable opinion given is dependent upon the study adhering to the conditions stated, which are based on the application document(s) submitted. It is appreciated that Principal Investigators may wish to challenge conditions or propose amendments to these. In that case, please consider the favourable opinion suspended, and simply make your case for amending or discarding conditions in writing as you would an application resubmission following ethical review.
host organisation, including the University of Portsmouth or supervisor, prior to the start of the study.

Wishing you every success in your research

[Signature]

Dr Paul Morris
Vice Chair, Science Faculty Ethics Committee

Annexes

A - Documents reviewed
B - After ethical review - Guidance for researchers

Information:

Professor Joanna Wakefield-Scurr - PhD Supervisor
Dr Jenny Burbage - PhD Supervisor
Holly Shawyer - Faculty Administrator

Statement of compliance

SFEC is constituted in accordance with the Governance Arrangements set out by the University of Portsmouth

After Ethical Review

If unfamiliar, please consult the advice After Ethical Review (Annex B), which gives detailed guidance on reporting requirements for studies with a favourable opinion, including, notifying substantial amendments, notification of serious breaches of the protocol, progress reports and notifying SFEC of the end of the study.

Feedback

You are invited to give your view of the service that you have received from the Faculty Ethics Committee. If you wish to make your views known please contact the administrator at ethics-sci@port.ac.uk

ANNEX A Documents reviewed

The documents ethically reviewed for this application

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-2017-011A SHARLAND PI Submission Email - Amendment - SFEC 2017-011</td>
<td></td>
<td>17 Feb 2017</td>
</tr>
<tr>
<td>B-2017-011A SHARLAND Amendment Form (1)</td>
<td></td>
<td>17 Feb 2017</td>
</tr>
<tr>
<td>C-2017-011TA SHARLAND Substantial Amendment - Emma Sharland v2</td>
<td></td>
<td>17 Feb 2017</td>
</tr>
</tbody>
</table>
FAVOURABLE OPINION

Protocol Title: Assessment of the validity and reliability of breast pain and bra comfort scales (SFEC 2014-004)

Date Reviewed: 13th January to 3rd February 2014

Dear Emma,

Thank you for resubmitting your protocol for ethical review and for the clarifications provided.

Your responses have been reviewed and I am pleased to inform you that your application has been given a favourable opinion by the Science Faculty Ethics Committee. Please notify us in the future of any substantial amendments that may be required and send us a final study report.

Good luck with the study.

Clare Eglin
Dept Sport & Exercise Science, Science Faculty Ethics Committee

CC -
Dr Chris Markham – Chair of SFEC
Dr Jim House – Vice Chair of SFEC
Holly Shawyer – Faculty Administrator
FAVOURABLE OPINION

Protocol Title: A methodological investigation into the validity and reliability of a breast pain survey and diary (SFEC 2014-033)

Date Reviewed: 12th to 21st May 2014

Dear Emma,

Thank you for resubmitting your protocol for ethical review and for the clarifications provided.

Your responses have been reviewed and I am pleased to inform you that your application has been given a favourable opinion by the Science Faculty Ethics Committee. Please notify us in the future of any substantial amendments that may be required and send us a final study report.

Good luck with the study.

Clare Eglin
Dept Sport & Exercise Science, Science Faculty Ethics Committee

CC -
Dr Chris Markham – Chair of SFEC
Dr Jim House – Vice Chair of SFEC
Holly Shawyer – Faculty Administrator
# Form UPR16

Research Ethics Review Checklist

Please include this completed form as an appendix to your thesis (see the Research Degrees Operational Handbook for more information)

<table>
<thead>
<tr>
<th>Postgraduate Research Student (PGRS) Information</th>
<th>Student ID: 448178</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGRS Name: Emma Louise Sharland</td>
<td></td>
</tr>
<tr>
<td>Department: DSES</td>
<td>First Supervisor: Professor Joanna Scurr</td>
</tr>
<tr>
<td>Start Date: October 2013</td>
<td></td>
</tr>
<tr>
<td>Study Mode and Route:</td>
<td></td>
</tr>
<tr>
<td>Part-time ☒</td>
<td>MPhil ☐</td>
</tr>
<tr>
<td>Full-time ☐</td>
<td>MD ☐</td>
</tr>
<tr>
<td>PhD ☒</td>
<td>Professional Doctorate ☐</td>
</tr>
</tbody>
</table>

| Title of Thesis:                                  | The development, piloting and evaluation of a bra intervention for women with larger breasts who are experiencing breast pain |
| Thesis Word Count: (excluding ancillary data)    | 61386 |

If you are unsure about any of the following, please contact the local representative on your Faculty Ethics Committee for advice. Please note that it is your responsibility to follow the University’s Ethics Policy and any relevant University, academic or professional guidelines in the conduct of your study. Although the Ethics Committee may have given your study a favourable opinion, the final responsibility for the ethical conduct of this work lies with the researcher(s).

UKRIKO Finished Research Checklist:
(If you would like to know more about the checklist, please see your Faculty or Departmental Ethics Committee rep or see the online version of the full checklist at: [http://www.ukro.org/what-we-do/code-of-practice-for-research/](http://www.ukro.org/what-we-do/code-of-practice-for-research/))

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) Have all contributions to knowledge been acknowledged?</td>
<td>☒</td>
<td>☐</td>
</tr>
<tr>
<td>c) Have you complied with all agreements relating to intellectual property, publication and authorship?</td>
<td>☒</td>
<td>☐</td>
</tr>
<tr>
<td>d) Has your research data been retained in a secure and accessible form and will it remain so for the required duration?</td>
<td>☒</td>
<td>☐</td>
</tr>
<tr>
<td>e) Does your research comply with all legal, ethical, and contractual requirements?</td>
<td>YES</td>
<td>☐</td>
</tr>
</tbody>
</table>

Candidate Statement:
I have considered the ethical dimensions of the above named research project, and have successfully obtained the necessary ethical approval(s)

Ethical review number(s) from Faculty Ethics Committee (or from NRES/SCREC):
SFEC 2014-034A
SFEC 2017-011A
SFEC 2014-004
SFEC 2014-336

If you have not submitted your work for ethical review, and/or you have answered ‘No’ to one or more of questions a) to e), please explain below why this is so:

Signed (PGRS): [Signature]
Date: 01 August 2018