It takes two? A randomised controlled pilot study to evaluate the feasibility and indicative effectiveness of joint physical activity consultations with colorectal cancer survivors and their partners

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Declaration

I, Pamela Katie Margaret Jenkins, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Acknowledgements

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Abstract

Title: A randomised controlled pilot study to assess the feasibility and indicative effectiveness of joint physical activity consultations with colorectal cancer survivors and their partners. ***Background***: Colorectal cancer (CRC) is the third most common cancer in Scotland and five-year survival has increased to 60% in the past 30 years. Evidence suggests that physical activity (PA) can improve cancer-specific and overall survival, as well as general and cancer-specific health outcomes in colorectal cancer survivors (CRC-Ss). Partners are a potential source of social support for CRC-Ss who may also benefit from increased PA. Couples have also been shown to share health behaviours. Therefore, this pilot study aimed to examine the feasibility of a randomised controlled trial of a joint PA intervention (PA consultations) with CRC-Ss and their partners. Specific objectives were to assess the feasibility of trial methods, the feasibility of the intervention and indicative effectiveness of the intervention on PA level and other health outcomes in CRC-Ss and their partners. ***Method***: This 6-month, parallel, randomised controlled pilot study took place in Glasgow. Participants were CRC-Ss who had completed all treatment for colorectal cancer in the previous 30 months and their partners. Participants were recruited by colorectal nurses from one hospital site and randomised using blocked SNOSE randomisation. This was not a blinded study. The intervention group received two home-based PA consultations, at baseline and three months. The control group received usual care. The main outcome measures were descriptions of trial protocol and intervention feasibility. Situational Analysis was conducted on intervention audio-recordings to inform feasibility. Data was also collected on PA level, mental well-being, quality of life, general self-efficacy and perceived relationship support. ***Results***: Over 15 weeks, 199 CRC-Ss were screened for eligibility; 49 (64.5%) eligible CRC-Ss were telephoned and 29 (59.1%) were recruited and randomised to the study along with their partners; 15 couples in the intervention group and 14 couples in the control. Retention to the study and compliance with the intervention were both 100%. Compliance with objective measures of PA was acceptable (77.6%), although there was some attrition in certain self-reported outcome data. There were no large indicative effects of the intervention on PA level or health outcomes, although small changes were found in PA level in the intervention

group. There were no adverse events related to study participation. ***Conclusions****:* Overall, trial protocol was feasible and joint PA consultations were feasible to deliver with CRC-Ss and their partners. There was a slight increase in PA at 3 months. Alone, this study does not provide sufficient evidence to proceed to a pilot trial. Future research should consider alternative sources of social support, alternative interventionist and systematic synthesis of feasibility research in this area.

Trials Registration number ISRCTN07465566

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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomised trial in a journal or conference abstract can be found in Appendix A

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List of Abbreviations

CRC – Colorectal cancer

CRC-S – Colorectal cancer survivor

DB – Decisional Balance

FCR – Fear of Cancer Recurrence

FCRI – Fear of Cancer Recurrence

GSE – General self-efficacy

HADS – Hospital Anxiety and Depression Scale

IPAQ – International Physical Activity Questionnaire

MVPA – Moderate to Vigorous Physical Activity

PA – Physical activity

POC – Processes of Change

QOL – Quality of life

SA – Situational Analysis

SE – Self-efficacy

SOC – Stage of Change

TTM – Transtheoretical Model of Behaviour Change

IT – Interdependence Theory

TPB – Theory of Planned Behaviour

SCT – Social Cognitive Theory

Chapter One: Introduction

Colorectal cancer (CRC) is the third most common cancer in both men and women in Scotland. Between 2003 and 2009 (when I began this study), 25611 people living in Scotland were diagnosed with CRC (ISD Scotland); between 2009 and 2015, a further 23291 were diagnosed (ISD Scotland). In the West of Scotland, the number of people diagnosed with CRC during these periods was 11683 and 10562 respectively. The World Cancer Research Fund and The American Institute of Cancer Research define a cancer survivor as "all people who are living with a diagnosis of cancer and those who have recovered from the disease" (WCRF and AICR, 2007). This definition includes any person with a diagnosis of cancer who is in pre-treatment, undergoing treatment, is post-treatment and in recovery and those who have secondary or second primary cancers. Survival from CRC has improved considerably in recent decades, with approximately 55% of patients now surviving to five years after diagnosis (Scottish Public Health Observatory, 2009). The five-year, age-standardised relative survival for people diagnosed with CRC in Scotland between 2007 and 2011 was 59.9% for males and 59.8% for females (ISD Scotland, 2015). At the end of 2015, 20,428 people in Scotland were living with, or 'survivors' of CRC (ISD Scotland).

Patients who go on to become long-term survivors of CRC (one, three, five and ten years post-diagnosis) can potentially have a recurrence of CRC, develop non-CRC cancers and/or suffer from comorbid conditions and long-term effects of treatment (Denlinger and Engstrrom, 2011). 43% of secondary CRCs occur more than two years post-diagnosis (Green et al, 2002 cited in Denlinger et al., 2011) and 80% of CRCs report at least one comorbidity (Jansen et al, 2010; Phipps et al., 2008 cited in Denlinger et al., 2011). Breathing problems, cardiovascular disease and depression are amongst the most common comorbidities for long-term CRC-Ss (Trentham-Dietz et al., 2003; Yabroff et al., 2004). There is therefore a need to ensure the best quality of life (QOL), health outcomes and chances of survival following diagnosis of CRC. Physical activity (PA) offers a non-pharmacological means of reducing cancer recurrence and the effects of comorbidities and improving QOL and health-related outcomes for CRC-S (Meyerhardt et al., 2009; Denlinger et al., 2011). Despite the potential benefits of PA, more than half of CRC-Ss are not meeting the current PA guidelines

(Aminisani et al., 2016). Further, there have been few randomised controlled trials of PA interventions with CRC-Ss and none to date that have included a partner or spouse. Partners provide and important source of social support for CRC-Ss and they too may benefit from a PA intervention. This study will therefore seek to address the following research questions:

- Is it feasible to conduct an RCT of a face-to-face PA intervention with CRC-Ss and their partners?
- Are joint PA consultations a feasible intervention for CRC-Ss and their partners?
- What is the likely impact of joint PA consultations on the PA levels and health outcomes of CRC-Ss and their partners?

In this thesis, I will present an account of how I addressed these research questions. Chapter Two presents a critical discussion of background literature pertaining to the research subject, including PA and the trajectory of CRC-survivorship, PA behaviour in CRC-Ss, evidence of PA interventions for CRC-Ss and the impact of a cancer diagnosis on the partners of CRC-Ss. In Chapter Three I will go on to critically discuss the theoretical frameworks that underpinned the study (The Transtheoretical Model of Behaviour Change and Interdependence Theory) and how these were applied to the intervention. Chapter Four will then lay out study aims and objectives before the intervention is presented in detail in Chapter Five. Chapters Six and Seven discuss study design and justification and study methodology respectively. In Chapter Seven I present the results of the pilot study, including the randomised controlled trial (RCT) and qualitative situational analysis (SA). Chapter Eight then turns to discussion of the study results followed by Chapter Nine, which discusses the results and locates them within the context of existing literature, as well as highlighting study limitations. Chapter Ten will provide a conclusion to the study and discuss suggested areas for future research.

Figure 1 outlines the original contribution of my PhD study and thesis.

Figure 1: Statement of Contribution to Knowledge

Statement of contribution to knowledge

What is already known on this subject?

- PA can increase cancer-specific and overall survival and improve physical and psychosocial health outcomes in CRC-Ss
- CRC-Ss report low levels of PA
- Partners are an important source of social support
- Health behaviours and health behaviour change are often more concordant between couples than between individuals in the general population

What does this study add?

- Evidence of the feasibility and indicative effectiveness of a joint PA intervention with CRC-Ss and their partners
- Theoretical synthesis of the Transtheoretical Model of Behaviour Change and Interdependence Theory, to apply an individual-level model of behaviour change in a dyadic setting
- The use of objective PA monitoring in a randomised controlled PA intervention study with CRC-Ss
- The first feasibility study to include Situational Analysis
- An Ordered Situational Map that highlights key themes, influences and interactions during joint PA consultations with CRC-Ss and their partners
- A critical exploration of feasibility studies, with suggestions of how they should be conducted synthesised from current literature

Chapter Two: Background

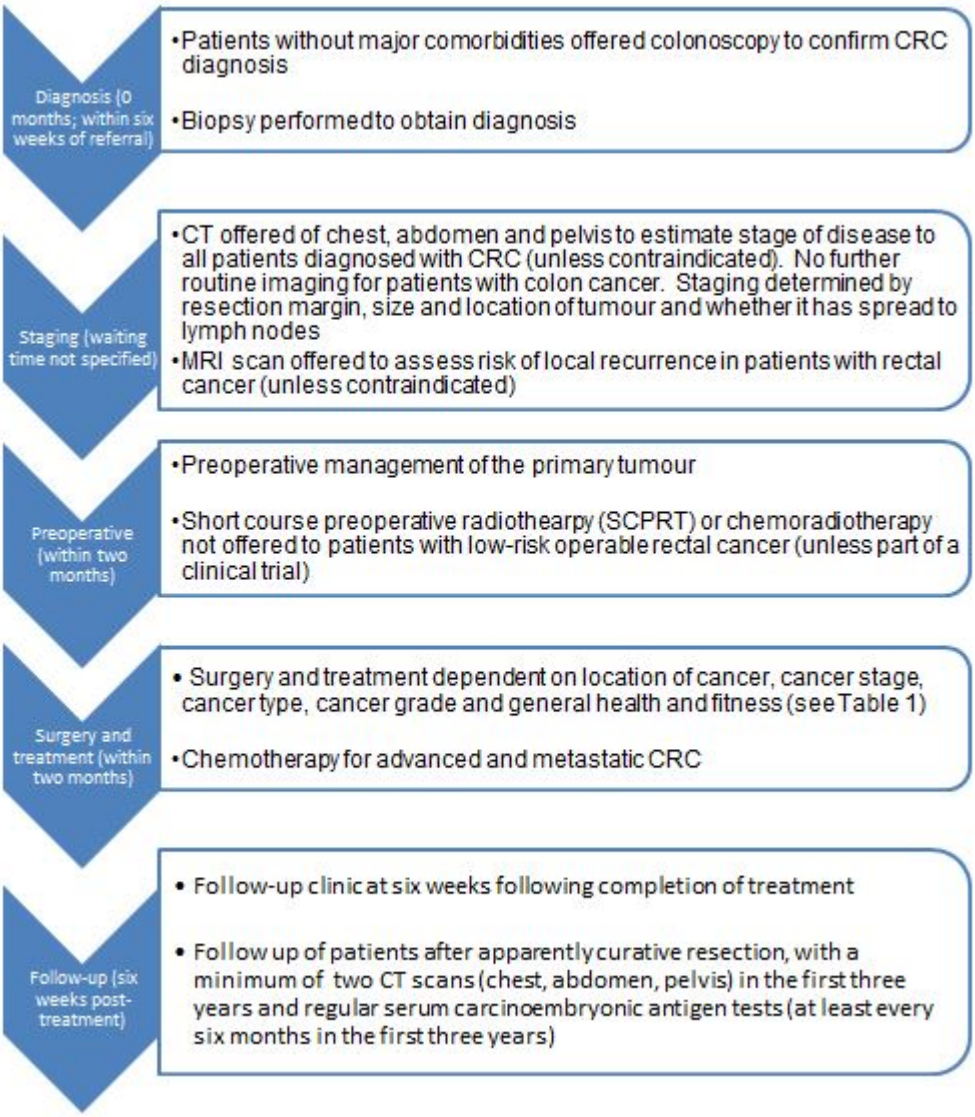
2.1: *PA and the Trajectory of CRC Survivorship*

2.1.1: CRC treatment and treatment-related side effects

In Scotland, urgent referral for colonoscopy or flexible sigmoidoscopy (collectively referred to as endoscopy) for suspected CRC, happens within two weeks. The subsequent timeline for those who receive a diagnosis of CRC is presented in Figure 2. The most common treatments for CRC include surgery, chemotherapy, radiotherapy, chemoradiotherapy and biological therapies (Cancer Research UK). Depending on the cancer, surgery options include surgical resection, laparoscopic surgery, colostomy and radiofrequency ablation (RFA). Due to anatomical differences in rectal and colon cancers, these diseases require different surgical and adjuvant treatment approaches (Tamas et al., 2015); therefore, the location of the CRC will determine what treatment is pursued. Chemoradiotherapy, for example, is only offered to rectal cancer patients and involves receiving chemotherapy and radiotherapy at the same time. Chemotherapy involves the use of cytotoxic drugs to destroy cancer cells, which circulate throughout the body in the bloodstream; these drugs are administered in tablet form or through a drip, infusion pump or injection (Cancer Research UK). Radiotherapy involves the use of radiation to destroy cancer cells – ordinarily through the use of high energy waves similar to x-rays (Cancer Research UK). Giving chemotherapy and radiotherapy treatment together has been shown to reduce risk of rectal cancer recurrence and also to shrink a tumour prior to surgical intervention (Tama et al., 2015). Treatment for colon cancer is determined by stage of tumour, details of which are presented in Table 1. Primarily, colon cancer is treated using a combination of surgery and chemotherapy. At more advanced stages, radiation is sometimes pursued. Targeted, biological therapies are another form of treatment for colon cancer - particularly those that have spread to other parts of the body - and are given either on their own or with chemotherapy. Biological therapies work to stop the blood supply to the cancer and are primarily given intravenously or occasionally in tablet form (Bowel Cancer UK).

Surgery and adjuvant therapies can cause a number of side-effects during treatment. Surgery related side-effects are wide-ranging depending on the procedure, although general physical side-effects include pain and tenderness, constipation or diarrhoea and stoma irritation; side effects of chemotherapy include vomiting, nausea, diarrhoea and neuropathy; side effects of radiotherapy include fatigue, skin reactions, upset stomach and loose bowel movements and the main treatment related side-effect of biological therapy is skin irritation (Cancer Research UK, Bowel Cancer UK).

Figure 2: CRC treatment timeline



Adapted from NICE Guidelines for the Diagnosis and Management of CRC and Bowel Cancer UK

Table 1: CRC treatment by stage

Stage T1	Stage T2	Stage T3	Stage T4	Advanced
Surgery is the main treatment People with T1 colon cancer do not need chemotherapy after surgery	Surgery to remove cancer Possible chemotherapy, depending on surgery results	Surgery to remove cancer Chemotherapy Chemo-radiotherapy (rectal cancer)	Doctor may recommend: Surgery Chemotherapy Radiotherapy Chemo-radiotherapy (rectal cancer) Biological therapy	Doctor may recommend: Surgery Chemotherapy Radiotherapy Chemo-radiotherapy (rectal cancer) Targeted cancer drugs

Side-effects of CRC surgery and treatment however, extend beyond the treatment itself; surgery and adjuvant therapies for CRC bring with them unique side effects for patients and survivors. Research has shown that physical and mental quality of life for CRC-Ss is inferior when compared with age-matched individuals without cancer (Derlinger et al., 2009). Issues and symptoms have been reported to be most prominent in the first three years following completion of treatment; however, long-term effects of treatment often persist and include fatigue, anxiety, depression, fear of cancer recurrence, low quality of life and physical problems, including pain, gastrointestinal problems and sensory neuropathy (Derlinger, 2009; Harrington et al., 2010). For example, Birigsson et al. (2007) found late adverse effects of radiotherapy to be common and severe, including bowel obstruction, gastrointestinal problems and low quality of life. A cross-sectional study by Bregendahl et al. (2013) further found severe bowel dysfunction to be a frequent long-term outcome after low anterior resection for rectal cancer in 41% of patients. A systematic review carried out by Cabilan et al. (2017), found functional status in CRC-Ss to decrease after treatment completion, particularly in older survivors. Further, physical activity was observed to decrease at six months after treatment (Cabilan et al., 2017).

Depression is one of the most commonly reported comorbidities in CRC-Ss; up to 37% of CRC-Ss report depressive and anxiety symptoms (Braamse et al., 2016; Tsunoda et al., 2005). In a systematic review of depression and anxiety in long-term cancer survivors, anxiety was reported as being more likely to affect long-term cancer survivors compared to healthy controls (Mitchell et al., 2013). In the

pooled sample of 51381 and 48964 cancer survivors, the prevalence of depression and anxiety was 11.6% (95% CI 7.7-16.2) and 17.9% (95% CI 12.8-23.6) respectively. This is supported by a recent literature review of 19 studies, totalling 92, 805 CRC-Ss, which found depression and anxiety prevalence ranging from 1.6%-57% and 1.0%-47.2% respectively in CRC-Ss (Peng et al., 2019). Psychosocial distress such as depression and anxiety can be debilitating and can have a profound detrimental impact on QOL in CRC-Ss (Aminisani et al., 2017; Santin et al., 2016).

Research has also shown treatment-related fatigue to be a significant problem for CRC-Ss that can persist long after completion of treatment (Thong et al; 2013). Thong et al. compared long-term fatigue amongst CRC-Ss with that of an age and sex-matched normative population; fatigue was found to be almost twice as common in CRC-Ss ($p<0.0001$). Further, short term survivors (<5 years post-diagnosis) had the highest mean fatigue scores. This concurs with Derlinger et al. (2009), who also found treatment-related effects to be more apparent in the short term (<3 years post-diagnosis).

FCR is the fear or worry that the cancer will return or progress in the same organ or in another part of the body (Simard et al., 2010). FCR is believed to be a universal concern for all cancer survivors and has been shown to be serious problem for CRC-Ss (Custers et al., 2016; Deimling et al., 2006). In a recent study of long-term CRC-Ss (median 5.1 years since completion of treatment), 38% were found to experience high levels of FCR, which was manifested in higher distress levels, post-traumatic stress symptoms and lower QOL (Custers et al., 2016). High FCR was not associated with any other demographic or medical variables (Custers et al., 2016). This evidence suggests that, long after surgery and treatment for CRC, survivors are suffering debilitating FCR that can detrimentally impact on their functioning and QOL. This is supported by Santin et al., (2015), who found that 40% of CRC-Ss report having one or more unmet need, including FCR, which adversely affected their health-related QOL. Further, FCR has been shown to cause some patients to avoid surveillance or demand more intensive surveillance than is advised (Thewes et al., 2012).

Daily function and general health in CRC-Ss are also impacted by the clinical and psychosocial side effects after completion of treatment (Jorgensen et al., 2015). The presence of a stoma, for example, has been associated with unemployment,

financial issues and diminished body image, and a negative impact on social functioning at one year post diagnosis (Jurgensen et al., 2015). Further, as discussed in Chapter One, CRC-Ss are at increased risk of cancer recurrence, secondary cancers and additional comorbidities following diagnosis and treatment, such as osteoporosis, cardiovascular disease, diabetes and obesity (Demark-Wahnefried et al., 2005; Lynch et al., 2016; Russell et al., 2015).

Follow-up and CRC survivorship care are a prominent issue; the period between completion of treatment and the development of a recurrence or death is often neglected and has been referred to as a time of transition from intensive hospital-based care back in to 'regular life' (Institute of Medicine and National Research Council). Late and long-term effects of CRC treatment can be considerable and are integral to patient outcome, as well as the interaction of these effects with daily function and general health (Jorgensen et al., 2015). Patients often have ongoing physiological, psychosocial and functional needs; assessment and management of these issues is important to achieving optimal outcomes for CRC-Ss and emphasises the need for secondary prevention strategies, such as PA, to improve these outcomes.

2.1.1: *The Impact of PA on cancer-related side-effects, recurrence and survival*

The positive benefits and effects of regular PA for health and well-being in the general population have been well documented and include: improved cardiorespiratory fitness (Lee, 2010), improved musculoskeletal function (Manini and Pahor, 2009), increased QOL (Acree et al, 2006), increased levels of and restorative effects on mental wellbeing (Fontaine, 2015) and improved cognitive function in older adults (Angevaren et al, 2008), amongst others. Further, PA has been shown to reduce the risk of developing CRC and other cancers, as well as other chronic diseases such as cardiovascular disease, diabetes, hypertension, obesity and depression (Warburton et al., 2006).

Evidence suggests that PA can also mitigate comorbidities and treatment effects and improve health outcomes in CRC-Ss. A systematic quantitative review and meta-analysis of 82 controlled PA trials in cancer survivors, reported PA to have a positive effect on a variety of health outcomes, both during and post-cancer treatment (Speck et al., 2010). In post-treatment studies (60%), significant effects of PA were observed for PA level (0.38, $p<0.0001$), aerobic fitness (0.32, $p=0.03$),

upper body strength (0.99, p<0.0001), lower body strength (0.90, p=0.024), body fat percentage (-0.18, p=0.006) and overall QOL (0.29, p=0.03). However, 83% of the studies included a diagnosis of breast cancer and only 9% of studies included a CRC diagnosis, highlighting the need for further research into the health benefits of PA interventions for CRC-Ss.

Research also suggests comorbidities such as cardiovascular disease can be diminished by increased PA participation. In a sample of 1596 cancer survivors, Kang and Courneya (2016) found that meeting PA amounting to ≥150 minutes walking per week, mitigated CVD risk factors compared to inactive cancer survivors, who were more likely to develop CVD (Kang et al., 2016). The odds ratio for having two or more CVD risk factors was lower for those meeting the PA guidelines than those who were completely inactive (0.55 [95% CI 0.39-0.77]) (Kang et al., 2016). This is supported by a longitudinal and cross-sectional study of 1966 CRC-Ss, in which those who were overweight and inactive were more likely to suffer from comorbid cardiovascular disease (Hawkes et al., 2011). Obesity at baseline predicted new diagnosis of hypertension (OR=2.20; 95% CI=1.09, 4.45) and new diagnosis of diabetes (OR=6.55; 95% CI=2.19, 19.53) and participants who watched more than 4 hours of television per day at baseline were more likely to develop ischaemic heart disease by 36 months (OR=5.51, 95% CI=1.86, 16.34) (Hawkes et al., 2011).

Evidence also suggests that PA is strongly associated with increased QOL in CRC-Ss (Tang et al., 2016; Gerritsen et al., 2016; Lynch et al., 2016) and that this population could therefore benefit from interventions to increase PA. An evidence review of PA and QOL in CRC-Ss reported PA to be consistently and positively associated with QOL in results from observational studies (Lynch et al., 2016). Higher levels of moderate to vigorous PA were linked to multiple QOL outcomes in 12 studies over the previous decade (Lynch et al., 2016). Analysis however, revealed no association between PA and QOL in intervention studies. As Lynch et al. highlight, almost all research into PA and QOL has relied on self-report measures of PA, which may explain this finding, therefore further research using objective monitoring of PA and impact on QOL in CRC-Ss is required.

A further systematic review and meta-analysis reported that exercise has a direct positive impact on QOL in patients with cancer (Gerritsen et al., 2016). Based on a meta-analysis of 16 RCTs, they found significant improvements in the

QOL of patients in exercise intervention groups compared to usual care (mean difference 5.55, 95% CI (3.19 to 7.90, p<0.001) (Gerritsen et al., 2016). Benefits of exercise were also found for secondary outcomes, including peak oxygen consumption, self-esteem and physical functioning. The study included a number of cancers, including colorectal, breast, prostate and lung cancer, therefore - given the small number of RCTs included in the review and the above finding of no effect of PA interventions on QOL in CRC-Ss – the evidence as applied to CRC-Ss must be interpreted cautiously. The findings, however, are encouraging and support the development of PA interventions for CRC-Ss. The results of a further cross-sectional study also indicate significant associations between PA and physical function in older, long-term CRC-Ss. In a sample of 843 cases, a direct, dose-dependent association was found between moderate PA and function (p<0.001); walking, gardening, housework and exercise were all found to be independently related to better physical function (Johnson et al. 2009). The current study will contribute to this literature by providing evidence of the indicative effectiveness of a PA intervention on QOL in CRC-Ss, using objective PA measures.

PA has been shown to provide symptom relief from depression and anxiety in cancer survivors (Schmitz et al., 2010; Speck et al., 2010; Craft et al., 2012; Brown et al., 2012). A systematic review and meta-analysis of exercise effects in cancer survivors found PA to have a significant positive effect on depressive symptoms, when comparing intervention to control groups using a random effects model (ES) in 21 RCTs (Craft et al., 2012). The overall mean ES was −0.22 (p = 0.04, CI −0.43, −0.009). Speck et al. (2010) however, found inconsistent impact of PA on depressive symptoms in cancer survivors; among a meta-analysis of six studies exercise was associated with only a small reduction in anxiety symptoms, *d*=−0.21 (95% CI: −0.39– −0.03) (Speck et al., 2010). This is contradicted by a meta-analysis of 34 RCTs, the findings of which support those of Craft et al. (2012), reporting PA to be associated with reduced depression in cancer survivors (−4.1, −6.5 to −1.8; p<0.01) (Fong et al., 2012). Overall however, intervention study evidence for PA and depression and anxiety in CRC-Ss is limited. Available evidence suggests PA intervention could potentially improve mental well-being and psychosocial outcomes such as anxiety and depression in CRC-Ss, but more research is needed. This study included depression and

anxiety outcomes measures in an attempt to add to this small, but important, body of literature.

In addition to the symptom-related post-treatment benefits of PA, research implies that PA continues to play a crucial role in CRC outcome and survivorship. Epidemiological evidence demonstrates that PA has a preventative role in reducing the incidence of CRC (Harriss et al., 2007; Harriss et al., 2009; Wolin et al., 2009). For example, a study by the National Institutes of Health (NIH) found an 18% reduction in colon cancer risk (relative risk 0.82; 95% CI, 0.73-0.82) amongst people aged 50-71 years who carried out PA 5 times a week compared with similarly aged people who never or rarely exercised (Denllinger and Engstrom, 2011; Howard et al., 2008). Further, a meta-analysis of 52 studies found an inverse association between PA and colon cancer in both men and women, with an overall relative risk of 0.76 (95% CI: 0.72-0.81) (Wolin et al., 2009). Evidence also suggests however, that PA continues to play a significant role across the trajectory of CRC, in reducing the risk of recurrence and improving the likelihood of cancer-specific and overall survival following diagnosis and treatment. Evaluation of PA and walking in a cohort of 526 colon and rectal cancer survivors found self-reported, pre-diagnosis regular PA (at least once per week) to confer improved cancer-specific survival at five years compared to those reporting no regular PA (73% and 61% respectively) (Haydon et al., 2006). PA was associated with an absolute improvement of 14% in overall survival and 12% in disease-specific survival at five years, compared with no regular PA (Haydon et al., 2006). Although the study assessed people at all stages of CRC, the benefits of PA were mostly observed in those with stage II-III tumours (Haydon et al., 2006).

A prospective observational study of 573 women with CRC found that those who increased their PA levels post-diagnosis had approximately a 50% reduction in CRC-specific and all-cause mortality (Meyerhardt et al., 2006). The study found a reduction in overall risk of mortality with PA roughly equivalent to four to five weekly 30 minute sessions of brisk walking and reduction in colorectal-specific mortality with PA double that duration or frequency (Meyerhardt et al., 2006). Further, this study found that the protective effects of PA post-diagnosis are independent of premorbid PA levels ie. before developing CRC (Demark-Wahnefried, 2006). A further prospective observational study of 832 patients with

stage III colon cancer found that higher levels of PA at 6 months following completion of treatment for stage III CRC conferred a significant improvement in disease-free survival (Meyerhardt et al., 2006). Post-diagnosis activity was also associated with reduction in cancer recurrence after 2.7 years (p=0.03) and overall survival (p=0.01). Men who are more physically active following a non-metastatic CRC diagnosis have also been observed to experience significantly decreased risk of CRC-specific and all-cause death (Meyerhardt et al., 2009). Men who engaged in the equivalent of 12-15 30-minute sessions of moderate intensity activity per week had more than a 50% lower risk of CRC-specific mortality compared with inactive men (Meyerhardt et al., 2009). In both of the above studies, the benefits of PA endured following adjustment for stage of cancer, age, BMI, year of diagnosis and tumour location (including rectum, evidence and survival of which is not often distinguished from colon in research literature).

Whilst clinically significant, the findings of Meyerhardt et al. (2006, 2006, 2009) resulted from observational studies and therefore cause and effect cannot be inferred. Further, more evidence is required as to what types, duration and intensity of PA are most beneficial to CRC-Ss, as well as the mechanisms through which PA impacts on CRC survival. Clinical pathways are unclear, but emerging evidence suggests that PA may influence insulin metabolism and inhibit the insulin-like growth factors associated with colorectal adenoma formation (a known precursor to CRC) (Sax et al., 2014; DeTroye et al., 2018).

Recent research supports the above studies, finding post diagnosis PA to decrease CRC recurrence and all cause mortality. A cohort study of 2293 adults diagnosed with CRC, found post-diagnosis recreational PA levels demonstrated a 48% multivariable relative risk reduction for all-cause mortality, when comparing the most active CRC-Ss with the least active ones (Campbell et al., 2013). Increased recreational PA before and after CRC diagnosis was associated with lower mortality, while increased leisure time spent sitting was associated with higher risk of death (Campbell et al.,2013).

A meta-analysis exploring the association between pre and post-diagnosis PA and cancer-specific and overall survival in CRC patients, found higher post-diagnosis PA levels to be associated with CRC-specific survival and a significant improvement in overall survival (Des Guetz et al., 2013). Across seven studies, hazard ratios for cancer specific survival - for higher versus lower pre and post-

diagnosis PA - were 0.61 (0.44–0.86) and 0.75 (0.62-0.91) respectively. The corresponding ratios for overall survival were 0.62 (0.54-0.71) and 0.74 (0.62-0.89) respectively (Des Guetz et al., 2013). This is supported by Je et al. (2013), who also found both pre-diagnosis and post-diagnosis PA were associated with reduced colorectal cancer-specific mortality and all-cause mortality in a meta-analysis of prospective cohort studies. Analysis showed that patients who took part in any pre-diagnosis PA had a risk ratio (RR) for CRC-specific mortality of 0.75 (95% CI: 0.65-0.87, $p< 0.001$) compared to those who did not engage in PA. Higher pre-diagnosis PA demonstrated a RR of 0.70 (95% CI: 0.56-0.87, $p = 0.002$). Engagement in any level of post-diagnosis PA had a CRC-specific RR of 0.74 (95% CI: 0.58-0.95, $p = 0.02$) and 0.65 (95% CI: 0.47-0.92, $p = 0.01$) for higher levels of PA compared to lower levels (Je et al., 2013). All-cause mortality was found to have similar inverse associations with pre and post diagnosis PA.

Recent analysis of has shown leisure time PA to be inversely associated with all-cause mortality and television watching associated with increased mortality risk in CRC-Ss. Engaging in ≥ 7 h/wk of leisure time PA was associated with a 31% lower all-cause mortality risk - independent of pre-diagnosis activity - compared to no activity (Arem et al., 2015). Pre-diagnosis, those who watched ≥5 hours of TV per day had a 22% increased risk of all-cause mortality, compared to those who watched 0-2 hours per day; more post-diagnosis TV watching was associated with a non-significant 25% increase in all-cause mortality risk (Arem et al., 2015).

The majority of research has focused on patients with earlier stage CRC. Recent research however, additionally suggests that people with metastatic CRC who are more physically active have better outcomes. A large clinical trial of 1231 patients about to begin chemotherapy found that those who reported engaging in PA equivalent to 30 minutes or more of moderate intensity active on daily basis, had a 19% reduction in mortality and a 16% reduction in cancer progression (Brendan et al., 2017). The impact of PA on metastatic CRC is largely unexplored, although early indications are promising of positive effect.

Overall, research appears to indicate that PA engagement equal to or more than 150 minutes of moderate intensity activity per week, before and after a diagnosis of CRC, is associated with decreased all-cause and CRC-specific

mortality in survivors compared with lower levels or no PA (Campbell et al., 2013; Winger et al., 2014; Arem et al., 2015).

2.1.3: *Physical Activity: Current Guidelines*

Although there are currently no official UK guidelines for PA and exercise in survivors, there are current American College of Sports Medicine (ACSM) PA guidelines for cancer survivors which should be followed. Table 2 presents the ACSM guidelines and contraindications for cancer survivors:

Table 2: *ACSM PA guidelines and contra-indications for cancer survivors**

	Aerobic	**Resistance**	**Flexibility**
US PA Guidelines for Americans (PAGA)	150 mins/wk moderate- intensity or 75 mins/wk of vigorous-intensity PA, or an equivalent combination	Muscle-strengthening activities of at least moderate-intensity at least 2 days/wk for each major muscle group	Stretch major muscle groups and tendons on days after activities are performed
Breast	Follow US PAGA	Start with supervised programme and progress slowly	Follow US PAGA
Prostate	Follow US PAGA	Follow US PAGA	Follow US PAGA
Colon	**Follow US PAGA**	**Follow US PAGA, except with stoma, where lower resistance and slower progression are recommended to avoid herniation**	**Follow US PAGA, taking care to avoid excess abdominal pressure if patient has ostomy**
Gynaecologic	Morbidly obese women may require additional supervision	Data on safety and benefits are not available for women with lower limb lymphedema	Follow US PAGA
Hematologic, no HSCT	Follow US PAGA	Follow US PAGA	Follow US PAGA
Hematologic, with HSCT	Recommend starting with lighter intensity and slower progression to greater intensity and duration	Follow US PAGA Resistance training may have particular benefits in this population	Follow US PAGA

**from Wolin et al. (2012), adapted from Schmitz et al. (2010) and Physical Activity Guidelines Advisory Committee 2008*

The current UK PA recommendations for the general population are:

- Aim to be active daily
- 150 minutes of moderate aerobic activity such as cycling or brisk walking every week eg. 30 minutes a day, five days a week
- Undertake PA to improve muscle strength on at least two days of the week.
- Minimise the amount of time spent being sedentary for extended periods

2.2: PA behaviour in CRC-Ss and health behaviour correlates

Despite the post-diagnosis benefits of PA, there exists a prevalence of physical inactivity in cancer survivors (Irwin, 2009). In a cross-sectional survey of 975 cancer survivors, less than half were physically active (Gjerset et al., 2010). Evidence suggests that only a small proportion of CRC-Ss meet the recommended guidelines for PA (Bellizzi et al., 2005) and that CRC-Ss are significantly more likely to report lower levels or lack of PA than other cancer populations (Rohan et al., 2015; Courneya et al., 2008). One study found that 89% of CRC-Ss are not meeting the recommended guidelines for PA (Aminisani et al., 2016).

In order to best increase PA levels amongst CRC-Ss, an understanding of the factors that affect PA in this population is required. Evidence suggests a range of symptom and function-related, clinical, psychosocial and sociodemographic correlates of PA behaviour in CRC-Ss (van Putten et al., 2016). A cross-sectional survey of 1371 CRC-Ss (mean age 69.5 years; 56% male; mean survival 3.9 years [SD 2.5 years]) found self-reported moderate to vigorous intensity PA (MVPA) to be positively associated with younger age, being male, being employed, being a non-smoker, low BMI and having no comorbidities ($p<0.05$) (Buffart et al., 2012). This suggests therefore that CRC-Ss who are older, overweight, female, smokers or who have one or more comorbidities are at increased risk of physical inactivity. Higher MVPA was also positively correlated with health-related QOL, although the direction of this association is uncertain.

Evidence of the correlates of PA in 185 CRC-Ss, as measured objectively using accelerometers, also reports younger age, employment and low BMI to be significantly correlated with MVPA, as well as higher family income (Lynch et al., 2016). However, overall levels of MVPA were low (mean 97 minutes per week)

and objective measurement of sedentary behaviour was high (mean 526.4 minutes per day; S.D. 93.2); gender, comorbidities and BMI were correlated with physical inactivity (Lynch et al., 2016). These objective results highlight the need for PA interventions in CRC-Ss. These findings are supported by previous research that similarly found CRC-Ss who are less well-educated, older, are overweight, smoke, or have comorbidities to be at higher risk of physical inactivity after treatment (Gjereset et al., 2010; Peddle et al., 2008).

A further study of the predictors of PA following a lifestyle intervention, found that CRC-Ss who were meeting the PA guidelines upon completion of the 12 month multiple health behaviour change intervention (CanChange), were more likely to be employed, ($p=0.004$), have had sufficient PA at baseline ($p<0.001$) and to have higher cancer-specific QOL ($p=0.031$) (Hawkes et al., 2015).

Self-efficacy: SE is also an important cognitive correlate of health behaviours that has been linked to the PA level of cancer survivors (Trinh et al., 2012; Speed-Andrews et al., 2012; Ungar et al., 2016). In a cross-sectional study of 600 CRC-Ss, there were moderate associations found between self-efficacy and PA level ($r = 0.69/r = 0.43$) (Speed-Andrews et al. 2012). This is supported by a meta-analysis by Stacey et al. (2015), which found self-efficacy to have a significant intervention effect for increased PA levels in cancer patients (standardised mean difference = 0.33) (Ungar et al., 2016). The NC STRIDES study (discussed previously) found SE to be significantly associated with PA scores ($p<.05$) and that where SE for meeting the PA guidelines was high, colon cancer survivors more likely to be in the 'action' stage of change for PA (James et al., 2006) (see Chapter Three for discussion of TTM).

Evidence of the impact of SE on behaviour change in cancer survivors however, is contentious. One prospective study of CRC-Ss found no association between SE and fruit and vegetable intake (Satia et al., 2004; Park et al., 2007) and another study of head and neck cancer survivors found no association between SE and behavioural changes in excessive alcohol consumption (Tromp et al., 2005). However, Courneya et al (2004) found that SE predicts PA behaviour change in a PA behaviour change intervention with CRC-Ss. They found that – along with exercise stage of change, employment status and treatment protocol – SE explained 39.6% of the variance in exercise adherence in a randomised trial of exercise in CRC-Ss ($beta=0.35$; $p=0.001$) (Courneya et al., 2004). Further, a

recent intervention study with breast and CRC patients, found baseline SE significantly predicted cancer patients' PA level after 4 weeks; relative weight analysis revealed that SE explained 38.4% of PA level (Ungar et al., 2016). Self-efficacy is an important cognitive factor that plays an important role in overcoming barriers to PA.

Depression and anxiety: As previously highlighted, depression is a common comorbidity reported by CRC-Ss. Evidence also suggests that psychosocial distress is correlated with physical inactivity in CRC-Ss and therefore CRC-Ss who suffer from anxiety and depression may be less likely to engage in positive PA behaviour (Chambers et al., 2009). In a prospective study of 1966 CRC-Ss, higher levels of psychological distress was associated with greater physical inactivity (relative risk ratio [RRR] = 1.12; 95% CI, 1.1-1.2) (Chambers et al., 2009). CRC-Ss who reported increased psychological distress over time were less likely to increase their PA over the same period ($p<0.001$) and CRC-Ss with higher anxiety were also less likely to report increased PA ($p=0.004$) (Chambers et al., 2009). This study used self-report measures of PA. A recent study of accelerometer-assessed PA and psychological health outcomes amongst CRC-Ss found no association between levels of moderate to vigorous intensity activity and depression in this population (Vallance et al., 2015); however, the study did find significant associations between those meeting the PA guidelines and decreased anxiety symptoms ($p=0.027$). Evidence suggests therefore, that PA can have a positive impact on psychological health and wellbeing outcomes in CRC-Ss.

Fear of Cancer Recurrence (FCR): FCR is an important correlate of health behaviour in CRC-Ss that has been shown to impact on PA levels (Fisher et al., 2016; Simard et al., 2013). In a survey of 10969 CRC-Ss, when compared with those meeting the PA guidelines, CRC-Ss who were doing some (OR 1.22; 95% CI 1.11, 1.35; $p<0.001$) or no PA (OR 1.28; CI 1.15, 1.42; $p<0.001$) reported higher levels of FCR (Fisher et al., 2016). There was a continuous, linear association between FCR and low levels of PA. As this was a cross-sectional study, the direction of the association between PA level and FCR could not be established. However, this is the largest population based study of FCR and CRC-Ss and indicates that CRC-Ss with lower levels of PA are more likely to experience FCR. PA levels could therefore be affected by or have a positive influence on FCR. This is an important finding for PA intervention development

with this population and, as such, the current study included a measure of FCR to establish change over time in this outcome following the intervention.

2.3: Evidence of PA interventions for CRC-Ss

Evidence suggests feasibility and favourable health outcomes of PA behaviour interventions with CRC-Ss. A feasibility study of a three-month personalised lifestyle programme for CRC-Cs who had completed treatment in the past 11 months, reported feasibility of recruitment (n=20), high study completion (90%) and high adherence to the intervention. Outcome data indicated a positive direction of change in self-reported, moderate intensity PA (+72 minutes per week, p=0.003) and in self-efficacy scores for improving PA (from 1223 to 1488; p=0.032). 14 participants also reported improved QOL (Anderson et al., 2010). Anderson et al. conclude that interventions with CRC-Ss should be personalised to suit all abilities, provide feedback on personal goals and encourage social support. These considerations have been applied to the current study. In 2009, when I began this study, Anderson et al. (2010) was the only available feasibility study pertaining to an intervention that addressed PA with CRC-Ss.

Preliminary results of a randomised controlled pilot study of a lifestyle intervention for CRCs, supports the feasibility of recruiting CRC-Ss to a PA behavioural intervention that could result in positive health outcomes (Bourke et al., 2011). The study recruited 18 CRC-Ss, who had completed surgery in the previous 6-24 months, to a combined exercise and diet programme or usual care. Adherence to the exercise components of the intervention was high (90% and 94%), attrition was low (6%) and improvements in the exercise behaviour of participants was recorded (p=0.68) (Bourke et al., 2011). Sellar et al. (2014) also report feasibility and improved health outcomes, in a feasibility study of a 12-week supervised exercise training programme. They reported low attrition (7%), high completion rate of study assessments (≥93%), high intervention adherence (91%, S.D. = 18) and significant improvements in health-related fitness in participants, including peak oxygen uptake (p<0.001) (Sellar et al., 2014).

All of these studies were limited by small sample size and lack of control group (with the exception of Bourke et al, who had a control group). Claims to

efficacy of interventions at improving health outcomes must therefore be interpreted with caution (see Chapter Six).

To date, there have been two evidence reviews that have assessed the literature for PA interventions with CRC-Ss. A systematic review of lifestyle interventions for patients with CRC, published between 2003 and June 2015, found PA interventions to be feasible and demonstrable of short-term improvements in health outcomes (Moug et al., 2017). The review identified 12 publications of RCTs of PA interventions carried out with 'patients' – or survivors* - of CRC (*please see survivor definition above). Two studies supported the feasibility of carrying out a PA intervention with pre-operative CRC 'patients' (Carli et al., 2010; Kim et al., 2009) and a further 10 were concerned with post-treatment PA interventions (Courneya et al., 2003; Hawkes et al., 2013; Ligibel et al., 2012; Morey et al., 2009; Demark-Wahnefried et al., 2012; Pinto et al., 2013; Campbell et al., 2009; Houberg et al., 2006; Houberg et al., 2005; Lynch et al., 2014). Interventions included home-based exercise programmes (Courneya et al, 2003) but were mainly home-based telephone guided PA interventions (eg. Hawkes et al., 2013; Ligibel et al., 2012; Demark-Wahnefried et al., 2012). The majority of studies reported low dropout rates (9%-19%) and good adherence and retention rates (Moug et al., 2017), suggesting acceptability to CRC 'patients'. Most of the studies also recorded improvements in short term physical and psychological health outcomes as a result of interventions, including increased levels of moderate PA at 12 months (≥30 min/day; p=0.003 [Moug et al., 2017; Hawkes et al., 2013]) and improved fatigue levels (EORTC QLQ C20; -6.6 points, 95% CI -12.3 to -0.9; p = 0.02 [Ligibel et al., 2012; Pinto et al., 2013; Moug et al., 2017]). Three papers reported no beneficial outcomes of post-treatment PA interventions with CRC 'patients' (Campbell et al., 2009; Houberg et al., 2005; Houberg et al., 2006).

This was a comprehensive and methodologically sound systematic review that supports PA intervention development with CRC-Ss. However, this review made no distinction between a survivor currently undergoing treatment for CRC and CRC-Ss who had completed surgery and/or treatment in the search criteria. The search term 'patients' therefore uncovered trials that were carried out with those still in treatment. The considerations of PA interventions carried out with pre, post and mid-treatment CRC-Ss are likely to be quite distinct, therefore this

limits the review, narrows the comparability of evidence and renders the confidence in the existing cumulative evidence weak. Further, the review methodology states that the primary outcome for eligible studies is to assess feasibility of lifestyle interventions with CRC patients, with secondary outcomes being to summarise any short and long-term health outcomes (Moug et al., 2017). However, studies which did not include feasibility as the primary outcome were included in the review (for example Courneya et al., 2003). Feasibility is therefore inferred from studies that have not explicitly sought to evaluate this outcome, but that report successfully carrying out an RCT of a lifestyle intervention with CRC survivors. This included studies that were not powered to detect meaningful differences between groups (Courneya et al., 2003), one of which was underpowered due to problems with recruitment (Pinto et al., 2013).

A further evidence review by Balrigan and Meyerhardt (2015), documented 6 RCTs of PA interventions aimed specifically at increasing PA behaviour, that included CRC-Ss, published between 2003 and 2014 (Backman et al., 2014; Lee et al., 2013; Cheville et al., 2013; Pinto et al., 2013; Ligibel et al., 2012 and Courneya et al., 2003). Three of these are included in the systematic review by Moug et al. (2017) discussed above (Pinto et al., 2013; Ligibel et al., 2012 and Courneya et al., 2003). The studies varied in sample size (23 -102 participants), disease stage and time since diagnosis and treatment. All of the interventions for the trials included recommendations to increase moderate to vigorous PA, delivered via approaches including supervised exercise sessions (Backman et al., 2014) and a home-based walking programme (Cheville et al., 2013). The review concurred with that of Moug et al. (2017), reporting that the trials found PA interventions to be feasible with CRC-Ss, with high levels of adherence (range 76%-93% [Blarigan et al., 2015). The majority of studies also found favourable effects of PA interventions on measured outcomes, including increased PA, QOL and cardiorespiratory fitness (Blarigan et al., 2015). However, this review is not reported as systematic in the methodology, which limits its conclusions. Further, there is a lack of transparency on the definition of feasibility and what outcomes were met for these trials to be qualified as feasible. Again, feasibility is being inferred from the outcomes of trials not designed to assess feasibility objectives.

Both of these reviews collated evidence from RCTs of PA interventions with CRC-Ss. Neither review included feasibility studies of PA interventions that were

non-randomised. Indeed, neither reviews reported having included 'feasibility' as a keyword during data searching. Therefore, non-randomised studies designed to assess the feasibility of a PA intervention with CRC-Ss would not have been included (including the two feasibility studies discussed above), yet both reviews make claims as to feasibility based on their findings. Feasibility is a distinct developmental phase of intervention research and distinguishing feasibility objectives, output and recommendations should be done based on transparent and robust feasibility outcome data (see Chapter Six).

An additional limitation of all of the RCTs documented in these reviews is that PA was assessed using self-report measures; there are no PA intervention studies with CRC-Ss that have assessed feasibility and/or PA as the primary outcome, using objective measures of PA.

Therefore, although these reviews demonstrate evidence of feasibility of PA intervention with CRC-Ss, their conclusions must be interpreted with caution.

In order to make my assessment of this literature more thorough and robust, I systematically updated the literature in November 2017, to check for recently published papers. I conducted a systematic search of Web of Science, Ovid and Medline, to update the results. I used similar search terms as in previously published reviews and included the terms 'colorectal cancer survivor' and 'feasibility.' Results returned 84 papers, from which I uncovered six relevant papers published between April 2015 and November 2017.

One paper reported results of a randomised trial to test the effects of gain versus loss-framed mailed brochures about PA, on the PA levels of 148 CRC-Ss who had completed primary treatment (Hirschey et al., 2016). The study found significant increases in PA in both study arms and that, at one month follow-up, approximately 25% of previously inactive participants increased their activity to such a point that they were now meeting the PA guidelines (Hirschey et al., 2016). Significant increases in PA were also found in both groups at 12 month follow-up; across all PA intensity levels, mean minutes of PA increased at one and 12 months relative to baseline (p-values<.0001) (Hirschey et al., 2016). Therefore, regardless of how PA messages are framed (either by gains or losses to be had), mailed PA brochures appear to be highly effective at increasing short and long-term PA in CRC-Ss (Hirschey et al., 2016). This study is one of the largest to date to have assessed the impact of a PA intervention in CRC-Ss and was successful

at recruiting and retaining a large sample of participants. However, the study did not address feasibility directly, nor did it have a control group, which limits causal inferences that can be made from the data. Another limitation is the use of self-reported measures of PA, rather than objective measures. There remains a void in the evidence base pertaining to PA interventions with CRC-Ss that assess change in PA over time using objective PA outcome measures.

Although not assessing changes in PA level, another paper reported an RCT of the influence of high-intensity and moderate-intensity exercise training in CRC-Ss which demonstrated positive effects on cardiorespiratory fitness (Devin et al., 2016). 47 post-treatment (27-38 months) CRC-Ss were randomised to receive either high intensity exercise or moderate intensity exercise, equivalent to the PA guidelines. High intensity exercise was shown to be a safe and feasible intervention that improved absolute ($p=0.016$) and relative ($p=0.021$) cardiorespiratory fitness in a clinically meaningful way, in comparison to current PA recommendations (Devin et al., 2016).

I found four recently published papers of studies that addressed the feasibility of PA interventions with CRC-Ss. (Courneya et al., 2016; Grimmett et al., 2015; Hubbard et al., 2016; Hubbard et al., 2016). The CHALLENGE Trial is a longitudinal study aiming to determine the causal effects of PA on CRC outcomes (Courneya et al., 2016). Between 2009 and 2014, 273 stage II and III CRC-Ss were recruited from 42 centres in Canada and Australia and randomised to receive either a structured exercise programme (SEP) or health education materials (HEM). Interim feasibility analysis of 250 participants who reached one-year follow-up, found that those in the SEP group reported an increase in recreational PA of 15.6 MET-hours per week compared with an increase of 5.1 MET-hours per week in the HEM group ($p=0.002$) (Courneya et al., 2016), meeting the criteria for trial continuation. Further, objective fitness improvements were also recorded in the SEP group relative to the HEM group, including 6-minute walk ($p<0.001$), 30 second chair stand ($p<0.001$) and predicted VO2max ($p=0.068$). This study supports the feasibility of structured PA interventions with CRC-Ss and demonstrates favourable PA and fitness outcomes. Again however, PA was not measured objectively. Also, recruitment of 273 participants over a six year period and 42 centres does not necessarily support the feasibility of recruitment to PA

intervention studies with CRC-Ss; this number is low relative to the period of recruitment and the number of sites.

Two further papers reported feasibility assessment of a pilot RCT of cardiac rehabilitation for post-surgical CRC-Ss (Hubbard et al., 2016; Hubbard et al., 2016). One paper reported the feasibility and acceptability of cardiac rehabilitation as an intervention for post-surgical CRC-Ss and the other reported the feasibility and acceptability of trial procedures. Quantitative and qualitative methods were employed in the pilot RCT to generate results. Cardiac rehabilitation was assessed as being a feasible and acceptable structured PA intervention for CRC-Ss; 62% of the 41 CRC-Ss who consented to participate in the study completed the intervention and 20 health professionals attended the cancer and exercise training course component, rating it highly (Hubbard et al., 2016). Qualitative results highlighted positive benefits of the intervention on CRC-S's confidence and motivation to exercise, as well as welcomed provision of peer support (Hubbard et al., 2016). Results regarding trial feasibility were less conclusive. Screening, eligibility and retention rates were 79%, 67%, and 93% respectively; consent rate was reported at 31%. Self-report outcome measure completion was initially high, although declined overtime from baseline to T1 and T2 (from 97.5% to 75% and 61%), indicating potential attrition in data in a definitive trial. This study is one of the first to assess the feasibility of a PA intervention RCT with CRC-Ss that employs accelerometers as an objective measure of PA; however, of the 69% of datasets collected from participants, 31% were removed as they did not meet the requirements for wear-time validation (Hubbard et al., 2016). The authors conclude progressing with caution with regards to conducting future PA intervention trials with CRC-Ss, as this study demonstrates potential recruitment bias and low adherence and attrition in outcome measures that could threaten the internal and external validity of future trials (Hubbard et al., 2016).

A further feasibility study that assessed a diet and PA intervention combining PA information and telephone consultations with CRC-Ss, found feasibility and acceptability of recruitment, intervention and indications of positive PA behaviour change (Grimmett et al., 2015). The study successfully recruited 29 participants and reported low attrition (14%) and high compliance with the intervention (96%), as well as significant improvements in self-reported PA (+52 minutes per week; p=.042) and objectively-measured PA (+70 minutes per week;

p= .004)(Grimmett et al., 2015). Further, a clinically meaningful improvement in quality of life was observed (p<.001) (Grimmett et al., 2015).

This study supports the findings of Anderson et al. (2010), who reported similar improvements in PA in a feasibility study of a personalised lifestyle programme for CRC-Ss (72 minutes per week). However, both studies were limited by lack of control group and small sample size. This is particularly important for the assessment of objective PA measures, which subsequently lack statistical power.

Despite increased research into PA behaviour interventions with CRC-Ss, there is still a relative dearth of PA intervention research aimed at promoting PA amongst CRC-Ss, compared to other cancer populations such as breast and prostate. This is perhaps due to a lack of longitudinal data linking PA with CRC survival; although prospective observational studies have established a positive association between PA and CRC-S survival (as discussed above), no RCTs have yet been carried out to confirm that PA lowers the risk of CRC recurrence or mortality (Van Blarigan and Meyerhardt, 2015). There is however, increasing evidence of the feasibility of PA interventions with CRC-Ss, though much is still unknown as to what form interventions should take, the feasibility of these interventions and trial protocols and the extent of the benefits to be gained. Progression from evidence of the potential to definitive conclusions about the efficacy of given PA interventions with CRC-Ss is reliant on a staged process of feasibility, piloting and full RCTs. Further, developments in PA interventions for CRC-Ss that are underpinned by health behaviour change theory are required. The evidence highlights the potential for PA interventions with CRC-Ss, but more extensive feasibility and pilot work is required to establish optimal intervention time, modes of PA intervention delivery, intervention development and the acceptability and likely success of trial protocols and methodology. Further, mixed methods assessment of PA interventions with CRC-Ss is also required.

2.4: CRC diagnosis – a 'teachable moment' for PA behaviour change?

There is evidence which suggests that a cancer diagnosis can serve as a motivator or 'cue' to cancer survivors to make positive health behaviour changes – referred to as a 'teachable moment' (McBride et al., 2000; Demark-Wahnefried et

al., 2005). An extensive systematic review of relevant studies from 1966 to 2004 revealed that cancer survivors often initiate health behaviour change with respect to diet, PA and smoking after diagnosis and that time after diagnosis is a pivotal juncture at which to introduce lifestyle interventions (Demark-Wahnefried et al., 2005). Sustaining behavioural changes however and reaching demographics of cancer survivors that are less likely to initiate these changes following diagnosis (older, male, less educated cancer survivors [Demark-Wahnefried et al., 2005]) are important considerations for intervention development.

A qualitative study of 81 CRC-Ss found greater perceived risk, worry and anxiety about cancer recurrence and health to be positively correlated with intentions to make health behaviour changes (Mullens et al., 2004). Shorter-term CRC-Ss reported higher risk perceptions and increased intrusive thoughts in comparison with longer-term survivors (Mullens et al., 2004). This suggests that proximity to diagnosis may be factor in making health behaviour changes. Contrarily to the findings of Fisher et al. (2016) discussed above however, greater perceived risk and anxiety about cancer recurrence correlated positively with intentions to make positive health behaviour changes (Mullens et al., 2004). Whether risk perception and FCR correlate positively or negatively with health behaviour change, evidence suggests that there is an association between the two and that diagnosis may be an optimal time to initiate behaviour change in cancer survivors.

A cross-sectional study of cancer survivors and their family and friends, The North Carolina Strategies to Improve Diet, Exercise and Screening Study (NC STRIDES) found that within the first 2 years since diagnosis, psychosocial factors such as SE and social support were positively associated with health behaviour amongst CRC-Ss. However, there was no difference in psychosocial and other health behaviour correlates between CRC-Ss and non-CRC-affected participants by approximately two years post-diagnosis (James et al., 2006). This suggests that an optimal time to introduce health behaviour change interventions for CRC-Ss could be within the first two years since diagnosis. Humpel et al. (2007) also found that cancer survivors were most likely to make positive health behaviour changes within the first six months since diagnosis.

Evidence remains unclear however, as to when cancer survivors are most receptive to heath behaviour interventions and change; ie. whether a ‘teachable

moment' happens at the point of diagnosis, shortly afterwards, during cancer treatment or within a given time after treatment (Rabin, 2009; Williams et al., 2013). There is relatively little evidence that a cancer diagnosis alone acts a trigger for positive health behaviour change (Fisher et al., 2016) and, as previously discussed, a significant proportion of cancer survivors are under or inactive, as well as overweight and heavy drinkers (Stevinson, 2010). One study of 7384 cancer survivors found that high-risk health behaviours such as lack of PA and smoking were most prevalent during the first year after diagnosis (Bellizzi, 2005). Recent findings of a cross-sectional survey of 1053 cancer survivors (including 106 CRC-Ss) however, indicated that proximity to diagnosis may provide a teachable moment to improve health behaviours and that time since diagnosis and symptom burden are relevant to these choices (Bluethmann et al., 2016). There is no definitive evidence of an interval at which it's optimal to intervene to assist in health behaviour change with cancer survivors. What is clear, however, is that colorectal and other cancer survivors need support in making lifestyle and behavioural changes that will benefit their health.

2.5: Barriers to PA for CRC-Ss

Understanding the barriers to and facilitators of PA for CRC-Ss is an important part of the development of effective PA behaviour change interventions. A recent survey of 495 CRC-Ss, who were six – 60 months post-diagnosis of non-metastatic CRC, revealed the most common barriers to PA were related to the cancer and it's treatment, such as fatigue (reported by 13% of patients), as well as age and mobility related comorbidities, such as impaired mobility and breathing difficulties (10%) (Fisher et al., 2016). Lack of time for PA was the most common general barrier (cited by 8% of participants). Those survivors who reported barriers to PA were found to be significantly less physically active - including when adjusting for numerous confounding variables - compared to participants reporting no barriers ($p = 0.012$; $p = 0.031$) (Fisher et al., 2016). 83% of participants reported perceiving at least one barrier to PA; 61% reported perceiving at least one benefit, including increased physical fitness (Fisher et al., 2016). These findings are similar to Lynch et al (2010), who also found disease-specific barriers to be the most commonly reported in telephone interviews with 538 CRC-Ss; at

five and 12 months post-diagnosis, disease specific barriers were significant predictors of PA level (OR = 0.93, 95% CI = 0.89, 0.98 and OR = 1.09, 95% CI = 1.03, 1.15 respectively [Lynch et al., 2010]). Personal attributes such as lack of enjoyment in PA, fear of injury and a belief that they were already active enough were also found to be barriers to PA for CRC-Ss (Lynch et al., 2010).

Recent qualitative research with CRC-Ss has also highlighted lay health beliefs and scepticism about the benefits of PA and a lack of motivation to be barriers to PA for CRC-Ss (Hardcastle et al., 2017), suggesting that CRC-Ss may need reinforcement of the importance and benefits of PA and other health behaviours.

Findings on the barriers and facilitators to PA in CRC-Ss are important for the development of theory-based interventions. The current intervention encourages participants to identify and work through solutions to perceived PA barriers as part of the consultation process (see Chapter Five and Appendices).

2.6: The impact of cancer diagnosis on the partners of CRC-Ss

The involvement of family members has been shown to provide social support for PA behaviour change in cancer survivors (Barber, 2013; Philips et al., 2013). Evidence also suggests however, that there may also be potential health benefits for family members.

Health behaviour: PA is a modifiable risk factor that contributes towards the prevention of cancer (World Cancer Research Fund, 2007). The partners of individuals living with CRC may share health risk behaviour related to PA and positive behaviour change in one partner may influence positive behaviour change in the other partner (Falba et al., 2008; Lewis et al., 2006; see Chapter Three). As discussed, PA and other health behaviours of CRC-Ss have been shown to be sub-optimal and at levels detrimental to health and wellbeing, therefore if partners share these behaviours they too may benefit from behavioural interventions. Partners of CRC-Ss may also perceive greater personal cancer risk (Humpel et al., 2007; Mazanec, 2015). Research has shown that individuals who have experienced cancer within their family perceive greater personal risk and are subsequently more likely to modify their own health behaviours (Robb et al., 2008). A study by Humpel et al. (2007) found that a cancer diagnosis motivated

the partners of cancer survivors to modify their diet and PA behaviour; 24.3% reported improved PA within one month of diagnosis (Humpel et al., 2007). Behaviour change was found to be related to partners' perceived personal cancer risk.

A cross-sectional correlational study of health behaviours in family members of patients completing cancer treatment, found high ratings for intention and perceived confidence to carry out healthy behaviours such as diet and moderate intensity PA (Mazanec et al., 2015). Family members also reported that the cancer experience had increased their awareness of their own cancer risk and motivated them to modify health behaviours. All family members in the study lived with the cancer survivor and 76.9% of the sample were spouses or partners (Mazanec et al., 2015). Evidence implies therefore, that a cancer diagnosis may also serve as a 'teachable moment' for the partners of CRC-Ss, making them a targetable population for PA intervention, as well as a source of social support.

Psychosocial effects: A cancer diagnosis has also been shown to have negative psychosocial effects on partners. Anxiety has been reported as being more likely to affect the spouses of long-term cancer survivors, compared to healthy controls (Mitchell et al., 2013). Depressed mood and poor QOL was found in a -+cross-sectional study of 910 spousal dyads to be high amongst spouses of cancer survivors and to have a 'spillover' effect to the other spouse (ie. depressed mood of the spouse had a knock-on effect on the mood of the cancer survivor)(Litzelman et al., 2016). This is an important consideration for intervention development, as these findings suggest that a concurrent approach to interventions considering psychosocial outcomes with cancer survivors and their partners may improve long-term outcomes. This is supported by Moser et al., 2013, who found – in a sample of 154 dyads – a significant proportion of cancer patients *and* their partners (up to 40%) reported high levels of anxiety, depression and low QOL (Moser et al., 2013).

Hence, the latest available evidence suggests that family members who are principally included in a PA intervention to support and enable PA behaviour change, may also benefit from receiving or being part of the intervention.

Chapter Three: Theoretical Frameworks

Two theoretical frameworks were applied in the design, delivery and evaluation of the study intervention: the Transtheoretical Model of behaviour change (TTM) (Prochaska and DiClemente, 1985) and Interdependence Theory (IT) (Kelly and Thibaut, 1978; Rusbult and Van Lange, 1996 cited in Glanz et al., 2002). This chapter will describe and discuss each of these theories and their application to the current intervention. Firstly, I will introduce the TTM and explain the structure and components of the model in the context of PA. The application of the TTM to PA behaviour will then be discussed, followed by a critical examination of evidence for the effectiveness of PA interventions supported by the TTM, including PA consultation. Interdependence Theory and the impact of dyadic relationships on health will then be discussed. Evidence of the effectiveness of dyadic interventions, with specific reference to partner and spousal-based health behaviour interventions, will be highlighted. How the TTM and Interdependence theory underpinned PA consultations in the current study will then be explained.

3.1*: The Transtheoretical model of Behaviour Change (TTM)*

The TTM is an integrative model of behaviour change, was conceived and first applied by Prochaska and DiClemente (1983) to understand smoking cessation in the 1980s. The TTM is an *individual*-level, stage-based model of behaviour change that integrates elements and principles from a variety of psychotherapeutic and behavioural theories, including Freudian, Skinnerian and Rogerian tradition (hence the name, *trans*theoretical) (Glanz et al., 2002). The TTM focuses on how motivated and ready an individual is to change a given behaviour and advocates that behaviour change occurs through a series of interrelated stages, as will be discussed below. Over the past 30 years, the use of the TTM has expanded and the model has been applied in intervention research to a broad range of health behaviours, including, for example, sedentary lifestyles and exercise, alcohol and substance misuse, diet, HIV/AIDS prevention, screening behaviours and medication compliance (Hutchison et al., 2009; Bridle et al., 2005).

PA consultation is an established and accepted form of intervention to support positive PA behaviour change (Loughlan et al., 1996; Rollnick et al., 2005; Kirk et al., 2007) and is discussed further in Chapter Five. The TTM is the

conceptual framework that underpins PA consultation and was therefore an integral theory to the pilot study. However, as will be discussed, I expanded on the social support components of the TTM to develop the use of PA consultation beyond the individual and apply it within a dyadic context.

3.1.1: *TTM theory and constructs*:

The following summary will highlight the key components of the TTM as applied to PA behaviour.

The TTM consists of four core constructs: Stages of Change (SOC), decisional balance, self-efficacy (SE) and Processes of Change (POC) (see Chapter Five for how these components were applied in the intervention).

Stages of Change: The TTM utilises a stage-based approach to behaviour change, where individuals progress through a series of interrelated stages known as the Stages of Change (SOC) (Prochaska and DiClemente, 1983). The SOC are the organisational concept of the TTM and refer to the sequential aspect of behaviour change. In the process of behaviour change, the TTM contends that individuals progress through psychologically and behaviourally defined stages, from an early stage at which one is not motivated to change a given behaviour, to a latter stage at which one has successfully modified and established positive behaviour change. There are five SOC that represent the stages through which an individual moves in adopting and maintaining a new behaviour. As applied to PA these are:

1. *Pre-contemplation* - the stage at which an individual is not intending to modify their PA behaviour within the next 6 months. Resistance to change is the defining characteristic of this SOC. An individual residing at this stage of the model would be currently inactive and have no intention of increasing their PA participation.
2. *Contemplation* - denotes the stage at which an individual is beginning to think about changing their PA behaviour. Someone contemplating PA would be currently inactive but thinking about increasing their PA participation in the next month and be taking steps to do so.

3. *Preparation* - the stage of change at which individuals are currently engaging in PA occasionally, though not regularly. Regular PA is defined as meeting the recommended guidelines for PA for adults of at least 150 minutes per week of moderate to vigorous intensity PA, with some PA being carried out every day (Chief Medical Officer, 2011).
4. *Action* - the stage in which people are regularly physically active but have been so for less than six months. People at this stage have successfully initiated behaviour change and positively modified their PA behaviour within the previous six months. People at this stage are meeting the recommended PA guidelines but are at high risk of relapsing back to an earlier SOC.
5. *Maintenance* - refers to the SOC at which individuals are regularly physically active (ie. meeting the PA guidelines), and have been so for longer than six months. At this stage, any problem PA behaviour has been successfully changed, the achievements of the *action* stage are reinforced and secured and attention turns to maintaining the healthy PA behaviour and the prevention of relapse.

Health behaviour change - from unhealthy to healthy behavioural practices - is a process for most people, during which they may experience set-backs and relapses to previous points of engaging in less healthy behaviour. Movement between stages of the model, therefore, is thought to be cyclical as opposed to linear (Marcus et al., 2003). As individuals move through the stages, they can regress back to an earlier stage of the model. Individuals in different SOC differ in their behaviour and level of motivational readiness to change. Figure 3 demonstrates the cyclical stages of behaviour change.

Processes of Change: At each SOC, there are numerous stage-matched processes that individuals apply - or that can be targeted by behaviour change interventions - to motivate and encourage behaviour change and progression through the stages. These are known as the Processes of Change (POC). There are 5 cognitive (or experiential) and 5 behavioural POC that have received the most empirical support as mediators of progression between the SOC (Prochaska et al. 2002). The POC in relation to PA are presented and described in Table 3. These processes result in strategies that help individuals to make and maintain

change in their behaviour. PA behaviour change is dependent on applying the relevant processes at the relevant SOC in order to aid transition from one SOC to the next (Marcus et al., 1996, cited in Glanz et al., 2002).

Figure 3: The Stages of Change

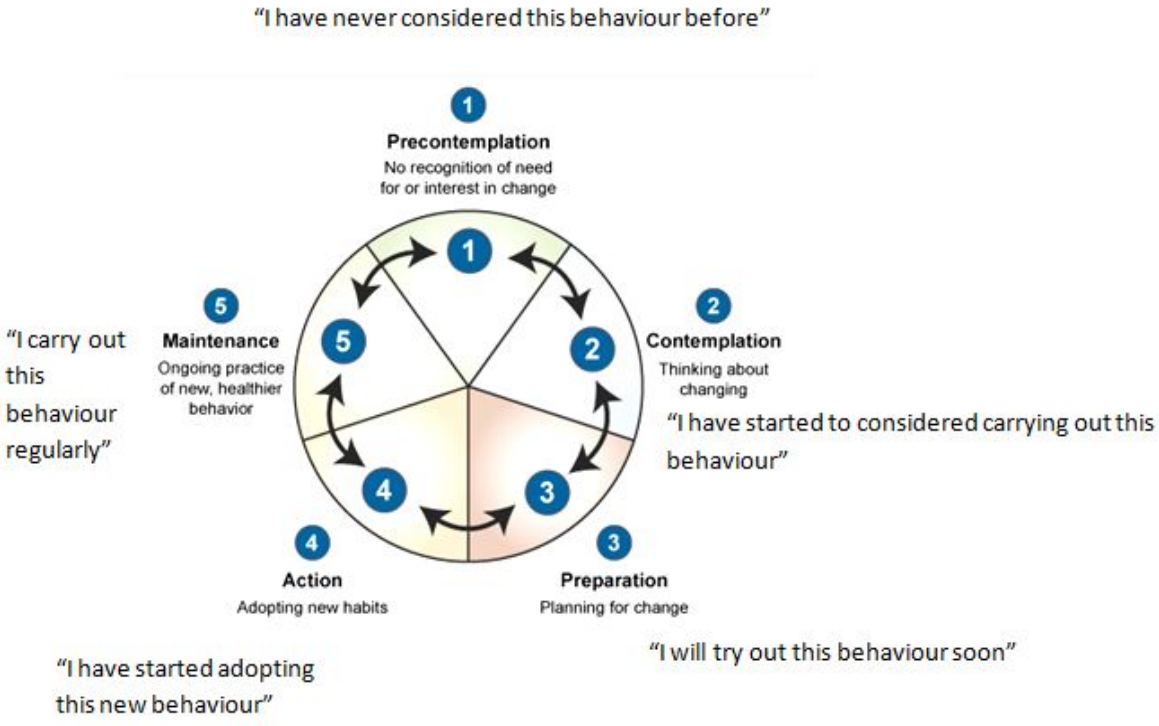


Table 3: *The Processes of Change as related to PA Behaviour*

PROCESS OF CHANGE	PROCESS DESCRIPTION
Cognitive processes:	
Consciousness raising	Increasing knowledge and understanding of the benefits of PA, means of engaging in more PA, ways of supporting PA behaviour change etc.
Dramatic relief	Increasing awareness of the risks of engaging in unhealthy PA behaviour
Self-re-evaluation	Cognitive and emotional assessment of one's self-image and values with and without participating in regular PA
Environmental re-evaluation	Cognitive and emotional assessment of the impact of one's unhealthy PA behaviour on others, such as family and friends, as well as one's own potential role in setting an example for others
Social liberation	An increase in social opportunities for PA and alternatives to inactivity, and empowerment for PA
Behavioural processes	
Self-liberation	Making a commitment to oneself to positively change PA behaviour
Helping relationships	Drawing on sources of social support, for example family members and friends, to facilitate and ease PA behaviour change
Counter-conditioning	Substituting unhealthy PA behaviour practices for healthier ones
Reinforcement management	Acknowledging and rewarding ones efforts to change in order to facilitate repetition of healthy responses
Stimulus control	Adding prompts and reminders to engage in PA and removing those to engage in unhealthy PA behaviour practices

Note: Adapted from Marcus, Rossi et al. (1992)

Decisional Balance (DB): DB denotes the weighing up of the benefits (pros) and the costs (cons) that an individual associates with increased PA participation as they move through the SOC. An example of a benefit of participating in regular PA might be the potential of increased PA to assist in weight loss or in aiding restful sleep; an example of a cost of participating in regular PA might be fear of injury or resulting loss of time with family members. DB varies greatly depending on what SOC an individual is in (Prochaska et al., 2004). An individual in pre-contemplation or contemplation SOC for example, is likely to have more cons than pros for increasing their PA than an individual in the preparation or action SOC.

Self-efficacy (SE): The SE construct of the TTM was incorporated from Bandura's SE theory (Bandura, 1994). Bandura defines SE as 'people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that effect their lives' (Bandura, 1994). SE influences people's feelings, thoughts, motivation and behaviour (Bandura, 1994). SE for PA, therefore, is the confidence that an individual feels in their ability to perform and positively change their PA behaviour, including overcoming barriers to PA and maintaining acquired PA behaviour changes. Bandura proposed that SE is the most important factor in behaviour change as it determines the extent of people's endeavours to change and subsequently how successful they are at doing so (Bandura, 1994). DiClemente (1981) hypothesised that SE relates directly to an individual's SOC. This was supported by research that has demonstrated increases in SE as an individual moves through the stages of change in smoking behaviour (DiClemente, 1981; DiClemente et al., 1985; Prochaska et al., 1985).

Table 4 summarises the relationship between the constructs of the TTM and the POC that mediate progression between the SOC. Figure 4 demonstrates the relationship between the TTM constructs.

Table 4: *Stage-matched constructs of the TTM*

Stages of Change	Processes of Change	Self-efficacy	Decisional Balance
Pre-contemplation	POC utilised significantly less than all other stages *Consciousness raising, dramatic relief, environmental re-evaluation* ↓ Experiential POC being utilised; less use of behavioural POC than preparation stage *Self-re-evaluation* ↓ Experiential POC being utilised similarly to those in contemplation stage; increased use of behavioural POC compared to those at contemplation stage *Self-liberation* ↓ Experiential and behavioural POC used more frequently than in preparation stage *Counter-conditioning, helping relationships, reinforcement management, stimulus control* ↓ Experiential POC used less frequently with greater use of behavioural POC than individuals in the action stage	Low	The cons of PA participation outweigh the pros
Contemplation		Low-Medium	Increased awareness of the pros but still highly aware of the cons
Preparation		Medium	Pros and cons beginning to balance out
Action		Medium-High	Pros of PA participation outweighing cons
Maintenance		High	Pros outweigh cons; greater weight given to the pros of PA participation

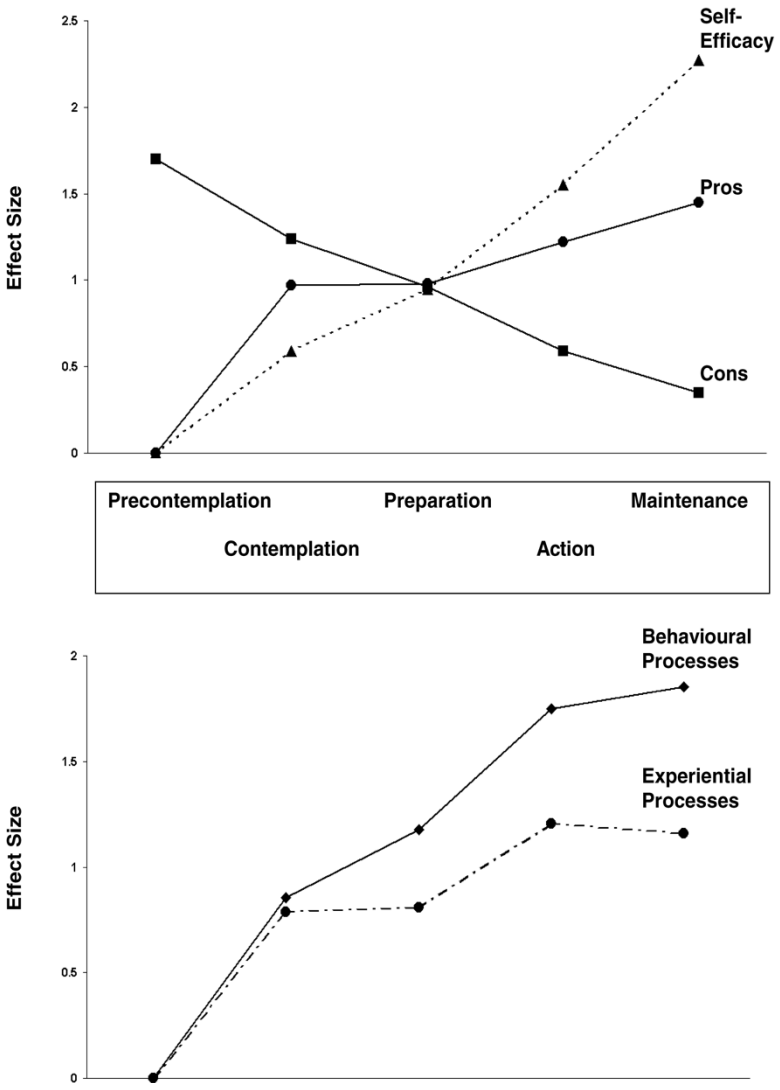


Figure 4. *The relationship between the SOC, decisional balance, SE and POC (Hughes and Mutrie, 2006, adapted from Marshall and Biddle, 2001)*

3.1.2: *Application of the TTM to PA behaviour*

The TTM posits that progression through the SOC is influenced by psychological and behavioural determinants: the POC, DB and SE. The TTM predicts that people at different SOC therefore require different interventions to elicit behaviour change (DiClemente and Prochaska, 1998). This section will examine the conceptual principles of the TTM as applied to PA behaviour and the evidence for the use of the TTM as an integrative model of PA behaviour for stage-targeted interventions.

Marcus et al. (1994) examined the application of the TTM to exercise behaviour. The results of the study found the SOC for exercise, SE for exercise

and DB to be predictive of PA level amongst 698 male and female worksite employees in Rhode Island, USA. SE was found to be the strongest mediator of SOC ($p<0.001$), PA level strongly correlated with SOC ($p<0.001$) and, overall, all constructs were found to be related significantly to PA at the 0.05 level or above (Marcus et al., 1994). On average, 43% of the variance in stage of exercise was explained by the constructs SE, pros and cons (i.e., DB) and an average 24% in variance of actual levels of PA explained by SOC (Marcus et al., 1994). Marcus et al. (1994) conclude that interventions targeted at specific SOC are supported.

Gorely and Gordon's (1995) examination of the TTM and exercise behaviour in 583 older adults aged 50-65 years similarly found SE to increase from pre-contemplation to maintenance SOC in exercise ($p<0.05$). However, Gorely and Gordon (1995) emphasise that it is not possible to determine whether SE is predictive of SOC and therefore exercise behaviour, or if increased SE results from increased experience with exercise as an individual progresses through the stages of change. Gorely and Gordon (1995) also demonstrated that individuals at different stages of change place differential emphasis on the positive and negative aspects of exercise participation. Those in the pre-contemplation stage perceived more cons to exercise participation and those in the maintenance stage perceived more pros ($p<0.05$) (Gorely and Gordon, 1995). This further supports the use of the decisional balance component of the TTM in PA interventions.

With regards to the POC, Marcus and Rossi et al. (1992) demonstrated that the 10 POC in the TTM (see Tables 1 and 2) could be applied to exercise behaviour and that 'experiential' POC are more relevant to understanding and predicting progress in earlier SOC and that 'behavioural' POC are more relevant to later SOC (Marcus, Rossi et al., 1992, cited in Glanz et al., 2002). Marcus et al. therefore argued that to successfully change exercise behaviour, the relevant, stage-matched POC should be adopted to facilitate movement between the stages. This was supported by a longitudinal study carried out by Lowther et al. (2007), which investigated the relationship between the POC construct of the TTM and movement through SOC in exercise behaviour in 312 participants from the general population. The study found self-liberation to be an important POC at each SOC, stimulus control to be important when progressing from contemplation to preparation SOC and social liberation and helping relationships associated with

progression from action to maintenance SOC (Lowther et al., 2007). This further suggests the potential of stage-matched interventions.

A meta-analysis by Marshall and Biddell (2001), which assessed the application of the TTM to PA and exercise, conversely suggests that the POC are not interactive with SOC and that the relevance of stage-matched POC is unclear. The analysis concludes that although individuals do use each of the 10 POC when trying to modify their PA behaviour, stage by process interactions are not evident and the importance of the POC is uncertain (Marshall et al., 2001). Although this contradicts evidence of stage-matched POC, it still provides support the use of POC in PA behaviour interventions.

A more recent systematic review of the literature by Spencer et al. (2007) concludes that the TTM can be applied to exercise behaviour. Overall they found that the majority of descriptive studies found associations between higher stages of change, increased SE, increased use of the POC and more positive perceptions of exercise (Spencer et al., 2007). However, the review found that in a number of studies, SOC was often assessed independently of the other constructs of the TTM (Spencer et al., 2007). The authors emphasise that it is essential to apply the entire TTM model and not just measures of exercise SOC. Ensuring that the appropriate POC are employed to aid progression through stages of change is integral to the successful application of the TTM to exercise or PA.

The validity of the constructs of the TTM for PA and their application to a variety of adult populations - including patients of heart surgery (Huang et al, 2015), older adults with type II diabetes (Kirk et al., 2010) and pregnant women (Haakstad et al., 2013) - has been demonstrated. However, many of these populations have been White, middle-class or predominantly female and studies have been mainly cross-sectional with small sample sizes. The principles and constructs of the TTM are not necessarily relevant to PA behaviour and PA behaviour change in all people. More evidence of the applicability of the TTM to different samples and representative populations is required, particularly in older adults over the age of 65 and in cancer populations. Further, a fuller understanding of the PA and exercise adoption process within the TTM is required. As Marcus et al. (1996) highlight for example, there are limitations in the explanatory capacity of the stages and processes of change. They acknowledge that the TTM does not determine whether ‘movement in the process of change

occurs before, concurrent with, or after the change in exercise stage of adoption' (Marcus, 1996: 200). This is a limitation of the TTM also discussed by Clarke and Eves (1997), who suggest that stage processes and behavioural outcomes may be 'reciprocally determined' and that this is not considered within the model (Clarke and Eves, 1997).

A distinction also needs to be made between the terms 'exercise' and 'physical activity' in relation to the applicability of the TTM. Caspersen et al. (1985) describe PA as any bodily movement produced by skeletal muscles which results in energy expenditure. PA in daily life can be categorized into, for example, occupational, lifestyle, household, sports or other activities. Exercise however, is a subset of PA that is planned, structured and repetitive and has a final or intermediate objective to improve or maintain physical fitness (Caspersen et al., 1985). Exercise and PA are frequently used interchangeably in research, when in fact they are distinguishable terms that have different meanings. As highlighted by Spencer et al. (2007), it is important to extricate 'exercise' from 'physical activity' in studies of the TTM, as the latter is a lifestyle definition that will place more people in the later stages of change (ie. action and maintenance) than will a definition of exercise (Spencer et al, 2007).

Overall, the use of the TTM for PA behaviour change is supported (Spencer et l., 2007; Marshall and Biddle, 2001; Lowther et al., 2007). Further research into *how* the various constructs of the model interact, mediators of stage transition and the relevance of the TTM to wider population groups will add further validity and rigour to the application of the model to PA.

3.1.3: *Effectiveness of stage-matched interventions promoting PA using the TTM*:

The TTM has been applied in numerous stage-based intervention studies targeting a wide range of health behaviours, including screening behaviour (e.g., Rakowski et al., 2004), smoking cessation (for example, Prochaska et al., 2001), diet (e.g., Horwath, 1999), alcohol abuse (e.g., Carbonari and DiClemente, 2000) and condom use (e.g., Schneider Jamner et al., 1997). For the purposes of the current study, discussion will focus on the practical application of the TTM in PA intervention studies aimed at improving PA behaviour.

Numerous studies aimed at improving PA participation have successfully adopted stage-based interventions based on the TTM (e.g., Kirk et al, 2004; Pinto et al., 2005). However, debate continues surrounding evidence of the efficacy and use of TTM-based interventions. Evidence points to short-term improvements in PA in TTM-based intervention studies, however evidence is lacking regarding longer-term improvements. A non-systematic critical review of the literature conducted by Adams and White (2003) found TTM-based PA promotion interventions to be effective in promoting PA adoption. This extensive review of 16 intervention programmes identified 15 randomised controlled trials (RCT) and one uncontrolled study based on the TTM. Eleven of the fifteen RCTs (73%) found TTM-based interventions to have a significant short-term effect (0-6 months) on stage progression, PA activity levels or both, when compared to control conditions. However, the review found that only two out of seven of the RCTs (29%) investigating longer term efficacy (more than 6 months) reported significant benefit of TTM-based interventions. This indicates the potential for long-term PA behaviour change following TTM-based interventions but highlights the need for further RCTs assessing the impact of these interventions beyond the short-term. Adams et al. conclude that PA interventions grounded in the TTM are more effective than non-staged interventions at increasing short-term PA participation but that preliminary findings on long-term effect are 'disappointing'.

A further review also found support for the effectiveness of stage-based interventions in exercise (Spencer et al., 2007). This systematic review assessed 31 stage-matched exercise interventions and 6 non-stage-matched interventions based on the TTM; 25 of the stage-matched interventions demonstrated success in forward stage progression and increased exercise participation amongst participants. In addition, 15 studies found stage-matched interventions to produce better outcomes than non-stage-matched interventions. Further, the studies assessed by the review adopted a range of intervention formats, including use of print materials, telephone and computer-based interaction, direct counselling and class meetings, which all demonstrated efficacy in movement through the SOC for exercise. Although the literature did not advocate one intervention format over another, the use of several approaches within an intervention was found to be more efficacious than a single intervention format. Spencer et al. conclude that

overall the evidence supports the use of stage-matched interventions for promoting exercise.

A systematic review by Bridle et al. (2005), however, suggests that TTM-based interventions have not sufficiently demonstrated efficacy in facilitating PA behaviour change. The review included seven interventions based on the TTM and found only one of these to show significant positive outcome of the intervention compared to usual care. These findings are supported by a critical review of stages of change outcome research in health behaviours by Whitelaw et al. (2000), who question the effectiveness of stage-matched interventions for PA and other health behaviours. Further, Adams and White (2005) conclude that there is little evidence to support any benefit of individualised, stage-based exercise promotion interventions in the long-term.

Bridle et al. (2005) also highlighted that in the majority of interventions based on the TTM, stages of change was cited as the dominant component of the model influencing intervention development. The SOC, however, is only one of four key constructs of the TTM (Velicer et al., 1998) which independently does not provide an explanation for behaviour change. The stages of change must be used in conjunction with the other components of the TTM (i.e., POC, SE and DB) for a theory based intervention with any explanatory capacity.

An extensive systematic review conducted by Hutchison et al. (2009) critically examined PA behaviour change interventions based on the TTM to determine efficacy of the interventions and to provide clarity as to exactly how the TTM is being used to develop PA interventions. Of 24 interventions reviewed, 18 (75%) reported statistically significant short-term findings and two reported statistically significant short and long-term findings. However, the review also observed that of the 24 interventions, only seven (29%) referred to all four constructs of the TTM when describing methodology and development. All 24 used the stages of change to inform intervention protocol. This finding is consistent with those of Bridle et al. (2005) and reinforces that few TTM-based intervention studies have addressed the multidimensional nature of the model in promoting PA behaviour change. SOC itself is not a theory therefore results of interventions that have used only SOC should be interpreted cautiously within the context of TTM.

Hutchison et al. (2009) did find however, that in 21% of the studies, additional theoretical frameworks had been applied to the interventions in addition to the TTM. This is in line with the recommendation made by Whitelaw et al. (2000) and Spencer et al. (2007), that the TTM not be applied to behaviour change in isolation, but alongside other theoretical models (as previously discussed) . Also, 71% of reviewed interventions were developed with reference to both the stages and processes of change constructs of the TTM, demonstrating recognition of the TTM beyond the SOC. Further, a limitation of these critiques of the TTM is that they focus too much criticism on the SOC component of the model in intervention research, which, although this may be accurate, fails to appraise the other constructs of the model. It may not be that the TTM-based interventions reviewed negatively were unsuccessful, but that they have failed to incorporate all dimensions of the TTM (Hutchison et al., 2009).

Hutchison et al. (2009) conclude that it is difficult to draw precise conclusions regarding TTM-based interventions, as the majority of studies reviewed did not employ all dimensions of the model and therefore cannot be accurately described as TTM-based. They acknowledge, however, that the majority of interventions reviewed did demonstrate significantly positive results and therefore that although interventions may fail to accurately represent the TTM, they are no less effective. Hutchison argues that future studies should develop interventions based on all four constructs of the TTM and not just SOC.

Although TTM-based interventions for PA have received criticism, application of the model to interventions aimed at promoting PA participation have produced some key findings and have demonstrated positive outcomes in PA behaviour change (e.g., Kirk et al, 2003). TTM-based interventions have considerable potential for PA behaviour change. In order to maximise this potential, I have compiled from the literature a list of factors to consider in the development of TTM-based interventions (see Figure 5). This is an important product of my literature review, which is part of my original contribution and that I have used to inform the development of the intervention in my study. These recommendations and their application to interventions provide an evidence-based link between theory and method. How the intervention trialled in the current study addresses these considerations is discussed below (section 3.3).

Figure 5: *Recommendations for PA interventions based on the TTM*

1. **Use in conjunction with other theoretical resources**: Whitelaw et al. (2000) suggest that the TTM cannot be considered as a single, consistent entity and needs to be used in association with other theoretical resources.

2. **Use all 4 dimensions of the TTM model in the development and implementation of a TTM-based intervention**: Spencer et al. (2007) emphasise the importance of applying the entire TTM model and not just the SOC construct independently, when developing and implementing intervention studies aimed at improving PA. The constructs of the model interact to achieve transition through the SOC, therefore adopting relevant POC and addressing self-efficacy for PA and perceived pros and cons is essential for achieving stage progression. Fully articulate how all dimensions of TTM model have been applied to the intervention (Hutchison et al., 2009).

3. **Define exercise v. physical activity**: It should be highlighted that the interchangeable use of the terms exercise and physical activity is a limitation of TTM-based approaches to PA and in evaluating and comparing the effectiveness of stage-based interventions. Clarity of definition between the two terms and how they are described and adopted within TTM-based intervention research is needed, as this could potentially affect a participants' SOC.

4. **Do not exclude individuals in pre-contemplation stage**: Whitelaw et al. (2000) discuss the ethical difficulties associated with interventions based on the SOC and the TTM, including the potential for individuals in the pre-contemplation SOC to be excluded from research (Whitelaw et al., 2007).

3.1.4: *The use of the TTM for PA and TTM-based PA interventions with cancer survivors*

There has been relatively little research into the application of the TTM to PA behaviour in cancer survivors and a complete absence of research into the application of the TTM to PA in CRC-Ss. A cross-sectional analysis by Clark et al. (2008) revealed significant correlations between SOC for PA, QOL and symptom management in long-term lung cancer survivors. A study by Green et al. (2014) examined the TTM for associations with adherence to PA and healthy diet in prostate and breast cancer survivors. Higher SE and SOC were both found to be associated with increased PA in these populations. Increased PA since diagnosis was also associated with higher SOC. Green et al. (2014) conclude that the application of the TTM to explain PA in prostate and breast cancer survivors can enhance the development of effective interventions for PA. However, the extent to which these findings can be extrapolated to the use of the TTM for PA with CRC-Ss is unknown. Research is needed into the use of the TTM as a theoretical framework for PA with CRC-Ss.

A recent systematic review and meta-analysis identified the TTM as including motivational and behavioural factors predictive of exercise adherence in cancer survivors (Husebo et al., 2012). The review found 5 studies that established statistically significant correlations between SOC for exercise and exercise adherence amongst cancer survivors. However, most of these were intervention studies based on the TTM and did not validate TTM constructs for use in PA behaviour with cancer survivors independently of the trial. This evidence therefore demonstrates the potential of the TTM as a theoretical framework for PA interventions with cancer survivors, but do not empirically support the application of the TTM to PA in these populations.

Only one study in the review focused on CRC-Ss (Courneya et al., 2004). The study used TTM constructs to examine predictors of exercise adherence and contamination in a previous trial of a PA intervention with CRC-Ss (Courneya et al., 2003). Results showed that exercise SOC was amongst the strongest predictors of exercise contamination in the control group ($r = 0.44$; $p = 0.031$) and of exercise adherence in the intervention group ($r = 0.43$; $p<0.001$). The study also found a significant interaction between baseline exercise SOC and group

assignment in predicting exercise rates (Courneya et al., 2004). Again, this demonstrates the potential use of the TTM for PA with CRC-Ss.

A number of intervention trials have used constructs from the TTM to target PA behaviour in cancer survivors, primarily breast cancer survivors (Pinto et al., 2005; Basen-Engquist et al., 2006; Mutrie et al., 2007) and prostate cancer survivors (Demark-Wahnefried et al, 2003; Taylor et al., 2006). Overall these studies demonstrated efficacy at increasing PA levels in the intervention group (for example, Pinto et al., 2005 and Mutrie et al., 2007).

However, there is a dearth of TTM-based PA intervention research with CRC-Ss. One study by Morey et al. (2009) examined the effects of a home-based diet and exercise intervention on the functional outcomes (including PA) of overweight, long-term colorectal, breast and prostate cancer survivors (n=641). The intervention – telephone counselling and mailed print materials – was based on the TTM and social cognitive theory. The study found that PA increased significantly in the intervention compared to the control arm ($p<0.001$ for mean arm difference).

Pinto et al. (2013) similarly carried out a home-based intervention to support PA in CRC-Ss. Findings from the study showed the telephone counselling intervention to significantly increase minutes of PA from baseline at three, six and 12 month time points ($\delta = 3.06$, 2.16 and 0.96 respectively; all $p<0.001$) in CRC-Ss who had completed treatment for Stage I-III colorectal cancer. However, this study fell short of the required sample size by two thirds; therefore the validity and reliability of the findings is highly questionable.

The TTM is a pragmatic model of behaviour change that offers a clear, person-centred approach for how people can change their behaviour. The TTM has been applied successfully in interventions with cancer and other populations to target PA and other heath behaviours (please see above). Further research is required, however, to fill the gap in the evidence base pertaining to the use of the TTM for PA in colorectal and other cancer survivors, as well as the effectiveness of studies based on the TTM with these populations. Further, the TTM should be combined with other theoretical resources to build on the TTM and its constructs and enhance it's potential for behaviour change. To that end, the current study combined the TTM with Interdependence Theory, to build on the social support component of the TTM and its application to PA consultations.

3.2: Interdependence Theory

3.2.1: Interdependence Theory and its constructs

Close interpersonal, social relationships are a key component of health and health behaviours (Ryff et al., 2001); as such, consideration of social relationships is integral to the development of effective health behaviour change interventions (Lewis et al., 2006). There is no individual theory that explains the influence that social relationships have on health, rather research in this area has been guided by a number of different conceptual models and theories - for example, Social Network Theory (Umberson et al., 2010) and Social Exchange Theory (Homans, 1958 cited in Glanz et al., 2002) - that have endeavoured to elucidate this link.

I will be focussing on Interdependence Theory, as this focuses on outcomes within dyadic relationships and suggests the concordance of and mutual influence over health behaviours within spousal relationships. This is pertinent to the current study, which includes partners in a joint PA intervention. Interdependence Theory also corresponds well with and enhances the social support and health-enhancing relationship concepts of the TTM. Interdependence Theory addresses three main concepts: interdependence, relationship interdependence and correspondence of outcomes (Lewis et al., 2002, cited in Glanz et al., 2002):
Interdependence denotes the means by which individuals influence one another's experiences, or the effect that an individual can have over another's beliefs, intentions, behaviours and outcomes (Rusbult and Van Lange, 1996, cited in Glanz et al., 2002). Health behaviour therefore, is influenced by the personal characteristics of the individual, the values and behaviour of their associate (or companion) and by the mutual influence of both the individual and their associate in the dyad during interaction. An individual's behaviour is never independent of the behaviour of the other individual in the dyad. With regards to health behaviour, an interacting dyad could be, for example, an individual and their doctor, an individual and a health behaviour interventionist or - as in the current study - an individual and their spouse or partner.

Hence, the current study assumes that the PA behaviour of CRC-S is reciprocally determined by the characteristics of the CRC-S, the PA values and behaviour of their partner and the mutual interaction between CRC-S and partner

to influence one another's PA behaviour. The PA behaviour of the CRC-S is not free from the PA behaviour of the partner and vice versa. Figure 5 conceptualises interdependence, social influence and interpersonal communication between dyads.

As discussed by Lewis et al (2002 cited in Glanz et al. 2002), interdependence is an important concept for two main reasons. First, interdependence suggests that health behaviour change interventions designed to target individuals should instead target interacting pairs of people. Second, how much of an individual's behaviour is determined by their own characteristics, how much is determined by the influence of a partner and how much is determined by the mutual influence of the interacting dyad is unknown and needs to be better understood in order to optimise the impact of behavioural interventions.
Relationship interdependence in Interdependence Theory emphasises the components of a relationship that combine to distinguish that relationship as either a close or a distant one. Relationship interdependence thus suggests that in a close relationship, characterised by, for example, feelings of attachment and equality, influence and communication is likely to be more efficacious in modifying health behaviour (Lewis et al cited in Glanz et al. 2002). In contrast, a relationship that is more detached, in which the dyad are dissociated from one another and interaction is characterised by, for example, tension and quarrelling, influence and communication are less likely to alter health behaviour.
Correspondence of outcomes is another key construct of Interdependence Theory that is important to consider for modifying health behaviours in relationships. Correspondence of outcomes is the extent to which a dyad in a relationship concur with regards to the joint outcomes of a given health behaviour (in this case, PA). If a dyad is correspondent in their outcomes, they are more likely to succeed in successfully altering health behaviour.

3.2.2: Empirical Evidence of Interdependence Theory and Health Behaviour

Manne et al. (2012) carried out a qualitative study, guided by the Interdependence Theory, which investigated couples' communication regarding CRC screening. Analysis revealed "direct partner effects", characterised by an intentional and clearly defined impact of one spouse on another with regards to

screening uptake decision-making. Analysis also revealed “indirect partner effects”, where the experience and decision-making of one spouse indirectly and unintentionally informed that of the other. This study highlights the influence a spouse can have in health-related choices and behaviours, as well how such choices can affect the quality of relationships. Manne et al. conclude that it might be prudent to include close others in interventions to improve CRC screening uptake.

This is reinforced by Barnett et al. (2013), who carried out an exploratory qualitative study into how spousal pairs influence each other’s PA behaviour in retirement. Barnett et al. found 3 core themes – spousal attitude towards PA, which was concordant with regards to general PA aspirations but divergent on the specificities of PA participation; spouses’ PA behaviour, in which joint PA participation was rare and, spousal support, which was viewed as important for uptake and maintenance of regular PA (Barnett et al., 2013). Barnett et al. also conclude that interventions should account for close relationships – specifically spousal ones – and aim to create supportive spousal environments for PA. This study also supports Interdependence Theory and its inclusion in the development of behaviour change interventions.

Research has shown high levels of correspondence in partners’ health behaviours in the general population, including PA behaviour, diet, alcohol consumption and smoking (Wilson, 2002; Stimpson et al., 2006; Meyler et al., 2007). A recent study also suggests that prostate cancer survivors and their spouses may influence one another’s diet and exercise behaviours (Myers-Virtue et al., 2015). Partners have also been shown to be very influential in reinforcing healthy behaviours (Joung, 1995). Other research has reported the strong influence of a spouse in short and long term smoking reduction and cessation (Westmass et al., 2002) and the influence of partners in one another’s use of health services (Falba et al., 2008). Spousal support has been associated with healthy behaviour change and suggested the most important source of support for middle-aged men (Campbell, 1991).

Coyne, Ellard and Smith et al. (1990) used IT to understand patient progress and adjustment following myocardial infarction. The study concluded that patient SE was reciprocally determined by both patient and spouse variables. These findings are important for health-behaviour interventions and suggest that

the inclusion of a spouse, partner or close other may improve outcomes. As Lewis et al (2001) note:

"The opportunity to recognise the interdependence of behavioural change and the goal of making knowledge, values and behaviours correspond within a family unit may be an advantage of family-focused over individual-focused behavioural change interventions."

Lewis et al., 2001: 246

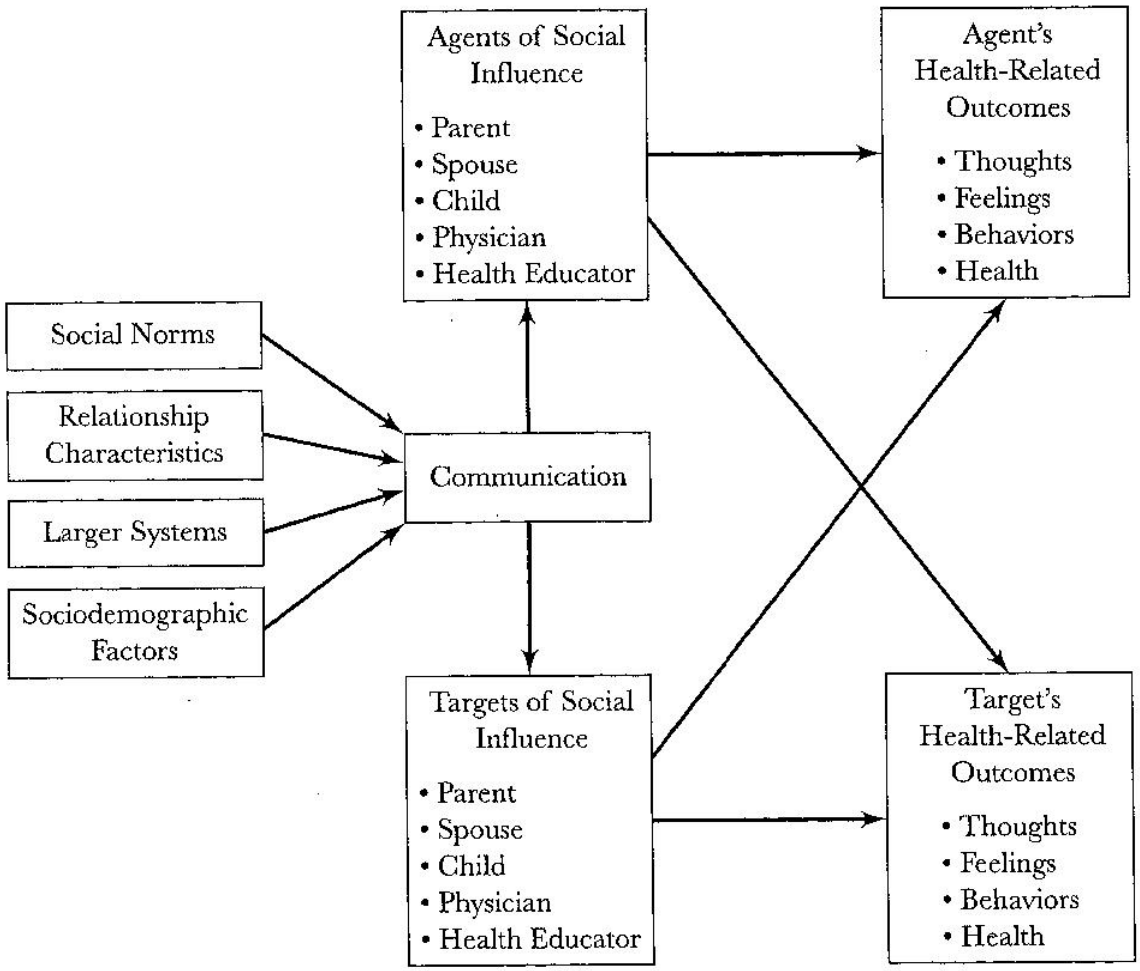


Figure 6: *Interdependence Model of Social Influence and Interpersonal Communication (Lewis et al., 2002 cited in Glanz et al. 2002)*

3.3*: The TTM, Interdependence Theory and PA consultations*

The above sections have described the two main theoretical models used in this study and appraised the empirical evidence. A key under-developed and under-researched component of TTM-based PA interventions is social support and 'helping relationships'. In this study, I addressed this limitation by drawing on a further theoretical resource - Interdependence Theory. In the following section, I describe how the TTM and IT were used in the PA intervention developed in my study.

The intervention carried out in this study was joint PA consultations. The intervention and its implementation are described in detail in Chapter Five. Here, I will highlight how the TTM and Interdependence Theory have been applied to and provide the theoretical underpinnings of joint PA consultations. This section is structured around the recommendations for interventions using the TTM, as presented in Figure 5 and discussed previously in section 3.1.3.

1. Use all 4 dimensions of the TTM model in the development and implementation of a TTM-based intervention:

PA consultation is a stage-targeted intervention that applies all four components of the TTM to PA behaviour change; PA consultation uses the constructs of the TTM interactively to achieve transition through the stages of change. PA consultation is a person-centred intervention that employs motivational interviewing (MI) techniques to guide participants through the process of positive PA behaviour change. MI is often related in research literature to the TTM, although no direct theoretical link has ever been established (Wilson et al., 2004). Further discussion of MI and how it was applied in the intervention can be found in Chapter Five.

The content of PA consultations can be found in Chapter Five. Firstly, during a PA consultation, an individual's SOC is assessed, by explaining what PA and PA intensity is and discussing, based on this information, at what SOC the participant resides. Once the relevant SOC has been determined, the consultation proceeds with stage-matched POC and DB methods (see Table 4) to help the individual progress through the SOC. Firstly, DB is applied by discussing and documenting

participants' perceived pros and cons of being physically active. Then, using MI techniques, participants are encouraged to address any barriers and find solutions to overcome them, thus increasing SE for PA. The consultation then goes on to address current PA level and identify opportunities and set short and longer term goals for increased PA, again to address and enhance SE for PA. Finally, participants are encouraged to discuss where they could source social support for PA; for example, who could be active with them, encourage them, help to overcome barriers etc. Although not a main construct of the TTM, social support is an important component of the theory and of PA consultations and will be discussed further below.

2. Use in conjunction with other theoretical resources:

The TTM was used in association with Interdependence Theory to develop PA consultations into dyadic ones. The TTM is an individual-level model of behaviour change that has never been applied in a dyadic setting. Social support is an important component of the TTM (as highlighted above). The helping relationships POC refers to seeking out and utilising social support available to an individual, in order to facilitate behaviour change. This is a fundamental component of PA consultations, during which participants discuss what support and from whom would assist them in becoming more physically active (in other words, what 'helping relationships' they need to exploit to assist them in positively modifying their PA behaviour). This could be, for example, from a friend, who supports the individual by being physically active with them. Social support could also be sourced from a relative, who positively reinforces increased physically activity behaviour or provides childcare in order to free up time for the individual to be more active. Or social support could come from a partner or spouse, who encourages and assists the individual in being more active. Interdependence Theory suggests concordance of health beliefs and behaviours within couples and that partners are an important source of social support. Therefore, my intervention built on the social support component of the TTM and developed the consultation process to include a spouse or partner. This study investigated the application of the TTM and PA consultations to couples, where each individual may or may not be at the same stage of behaviour change. The couples in the intervention arm of

the study are treated as individuals, residing at their own SOC, within the consultation. The consultation is designed to improve the PA levels and other health outcomes of the partner as well as the CRC-S. The PA consultations are manipulating correlates of health behaviour identified in the TTM and Interdependence Theory. As Prochaska et al. (2002) state, the TTM is a "dynamic theory of change. It must remain open to modifications and enhancements..." (Prochaska et al. 2002, cited in Glanz et al., 2002: 116).

3. Define exercise v. physical activity:

During the consultation, I discussed with participants the difference between PA and exercise. The term PA appeared on all documentation to do with the study. PA was defined to participants as any activity carried out throughout the day that involved movement, such as walking, housework, gardening and taking the stairs. Exercise was defined as a specific form of PA that is planned and purposeful, such as cycling, swimming or running. During the PA consultation and goal-setting, both PA and exercise could be discussed and adopted by participants as they navigated through the consultation. The intervention was described using the term PA; SOC was assessed based on participants' level of PA, not exercise.

4. Do not exclude individuals in pre-contemplation stage:

In order to overcome ethical difficulties associated with the potential for interventions based on the TTM to exclude those in the pre-contemplation SOC (as discussed by Whitelaw et al., 2000), participants in the pre-contemplation SOC who were not meeting the recommended PA guidelines and had not begun to think about increasing their PA, were eligible for inclusion in this study.

3.4 The use and effectiveness of alternative theoretical frameworks

This study employed an established, TTM theory-based intervention (PA consultation) and augmented it by using it in conjunction with Interdependence Theory, to enhance the social support component of the intervention. In order to achieve fidelity to the intervention, it was not appropriate to fundamentally change the theoretical framework or underpinnings of the consultations. To the best of my

knowledge, there are no PA consultation interventions supported by other health behaviour theories or indeed integrated with Interdependence Theory. It is important, however, to acknowledge alternative health behaviour models and why they were not applicable to this intervention. There are a wide range of health behaviour theories; in this section I will focus on the Theory of Planned Behaviour and Social Cognitive Theory.

The Theory of Planned Behaviour (TPB)

The TPB (Azjen, 1991), posits that individuals will make logical, reasoned decisions about engaging in a given health behaviour based on available information about that behaviour. According to the TPB, whether or not an individual performs, for example, PA, is dependent upon their intention and motivation to engage in PA and the level of control they perceive themselves to have over their PA behaviour. Intention to engage is influenced by the importance an individual places on PA, how easy they perceive performing PA to be (perceived behavioural control) and the perceptions of others (Azjen, 1991). Perceived control is determined by control beliefs about the presence or absence of facilitators and barriers to taking part in PA. The TPB has been successfully applied to interventions tackling a wide range of health behaviours amongst diverse populations, including fruit and vegetable consumption amongst children (Gratton et al., 2007); the PA and healthy eating behaviours of people with type II diabetes or cardiovascular disease (White et al., 2012; Blanchard et al., 2003); screening uptake (Booth, 2014) and physical activity and sexual health behaviours amongst young people and adolescent girls (Cooke et al., 2014; Karimi-Shahanjarini et al., 2013). However, to date, there has been little research on the application of the TPB within cancer studies; research has primarily focused on the use of TPB as a predictive tool for understanding PA behavioural intention and adherence amongst cancer populations. For example, Courneya et al. (1999) found the TPB to be a useful model for understanding exercise motivation in post-surgical CRC-Ss; regression analysis demonstrated pre-diagnosis intention and exercise level, as well as attitude, to predict post-surgical exercise. Courneya et al. conclude the TPB to be a viable framework upon which to base interventions to promote exercise in CRC-Ss. A further study of exercise behaviour found intention to exercise to be a strong predictor of overall exercise in RCTs with

cancer survivors (Courneya et al., 2002). Specifically, this study found exercise contamination within the RCT to correlate with pre-existing intention, whilst exercise adherence within the trial could be predicted by perceived behavioural control. Courneya et al. suggest therefore, that the TPB is useful in screening for intention to exercise in intervention research as it is predictive of performance in RCTs. This is supported by a further study by Courneya et al. (2004), which found perceived behavioural control and intention to be predictive of exercise adherence and contamination respectively, in an RCT of exercise in CRC-Ss. However, data from two recent cross-sectional studies with head and neck cancer survivors found PA intention and behaviour were not adequately explained by the TPB and its pathways (Buffart et al., 2018). Buffart et al. found a large proportion variance in PA intention and behaviour unexplained by the TPB (22.9% and 16.1% respectively) and therefore recommend the need for better, alternative behaviour change models to guide the development of PA interventions, particularly with older cancer populations.

There is a dearth in applications of the TPB to intervention research with cancer survivors. A recent pilot study of an online TPB-based PA behaviour change programme (UCAN) found the intervention to have negative effects on motivational variables from the TPB amongst breast, prostate and colorectal cancer survivors, including intention, perceived behavioural control and underlying beliefs (Forbes et al., 2017). Having conducted a (non-systematic) search of PubMed, Medline and Embase, this was the only behaviour change intervention with cancer survivors found to have applied the TPB. Further research is needed into the application of this model to PA behaviour in cancer survivors.

The TPB provides a potential framework to empirically identify factors for intervention development. However, identifying which control beliefs are affecting perceived behavioural intention is problematic and trying to affect positive change in targeted beliefs may detrimentally impact on other important beliefs (Glanz et al., 2002). Further, positive changes in control beliefs will not bring about increased PA if an individual is not motivated towards PA in the first place. Equally, a person who is motivated to take part in PA will not implement their intention if they do not feel in control of factors perceived as contingent to their participation.

There was little available evidence upon which to build or modify the current intervention using the TPB for this population. Further, the constructs of the TPB do not pertain to the aims of the current study nor provide a rationale for enhancing social support; TPB is an individual-level model of behaviour change and as such is not relevant, unlike Interdependence Theory. However, the TPB is an attitudinal model that has the potential to moderate and/or interact with elements of the TTM and future research may wish to investigate this. Courneya et al. (2000) concluded from a cross-sectional survey with undergraduate students that an integrated TPB and TTM model produced important theoretical insights into how and why people successfully change their exercise behaviour. There have, however, been few experimental and longitudinal studies that have interrogated this link. Future interventions may wish to investigate the juncture between these two theories and the potential of a combined approach; components of the TPB may provide useful insight into underlying individual influences on PA behaviour.

Social Cognitive Theory (SCT)

SCT (Bandura 1997; 2001) is a comprehensive model of behaviour change that addresses both psychosocial influences on and methods for bringing about health behaviour change (Baranowski et al., 2002). SCT suggests that health behaviour is influenced by the interaction between individual experiences, the actions of others and environmental factors. Underlying individual cognitive variables include the ability to symbolise and anticipate the outcomes of behaviour, to learn by observing others, to have confidence in carrying out behaviour (self-efficacy), to self-determine or self-regulate behaviour and the ability to reflect on experience (Bandura, 1997).

Previous research has shown SCT constructs to explain 40% - 71% of the variance in PA behaviour in adults (White et al., 2011; Ayotte et al., 2010) and women with breast cancer (Phillips et al., 2012), whilst systematic reviews of intervention components have associated SCT constructs with increased PA (Greaves et al., 2011; Michie et al., 2009). Amongst cancer survivors, previous meta-analysis reported improvements in depression, PA and QOL in health outcome intervention studies based on SCT (Graves et al., 2003). More recently,

SCT has been successfully applied as a theoretical framework and used to guide interventions aiming to influence these underlying variables to bring about behaviour change in cancer survivors. A systematic review and meta-analysis of SCT-based PA and nutrition behaviour change interventions found SCT to be safe and to show promise at positively influencing PA and dietary behaviours in cancer survivors (Stacey et al., 2015). The review included 12 PA intervention studies, of mixed cancer diagnoses, both during and after completion of cancer treatment. A small-to-medium effect size of 0.33 supported the efficacy of SCT-based interventions in changing PA behaviour. However, self-efficacy and goal-setting were found to be the only constructs associated with positive PA behaviour change and SCT theoretical constructs did not significantly mediate intervention effects. Further, SCT constructs were found to be inadequately operationalised, untested and underreported (Stacey et al., 2015). Two recent PA studies with cancer survivors have shown limited impact of SCT-based interventions. SCT constructs were operationalised in the Exercise and Nutrition Routine Improving Cancer Health (ENRICH) intervention, to assess whether these were mediators of behaviour change in 174 cancer survivors and carers. With the exception of behavioural goal – which had a significant mediating effect on step count, explaining 22% of intervention effect at 20 weeks – SCT constructs were found to have limited impact on objectively-assessed step counts in participants (Stacey et al., 2016). A further walking intervention study, Steps Toward Improving Diet and Exercise among cancer survivors (STRIDE), found no additional impact of an online support resource designed according to SCT. Participants in the pedometer intervention increased step count and physical fitness at three months, whether or not they had received online support and step goal setting (Frensham et al., 2018).

When my study was conceived, there was little evidence as to whether interventions based on SCT had a positive impact on PA behaviour in cancer survivors, nor which constructs and intervention characteristics were associated with PA behaviour change using SCT. Recent evidence in this area is varied in conclusion. SCT is an extensive model of behaviour change that consists of a comprehensive number of constructs that allow the model to be applied to broad and varied phenomena. On the one hand, this extends the utility and scope of SCT as a behaviour change model and permits wide-ranging intervention

research; however, the constructs of SCT are so numerous that this, conversely, has the potential to undermine the integrity of the model by making it malleable and applicable to almost any situation (Baranowski et al., 2002). It is essential to interrogate the model and the situations to which it is applied and, as Baranowski et al. (2002) reinforce, to limit claims of efficacy to situations and phenomena for which there is empirical evidence. As discussed, my intervention was an established intervention based on the TTM and, although there are commonalities between SCT and the TTM – such as self-efficacy – incorporation of SCT was not appropriate for this intervention. There was no available evidence to support the use of SCT with my population group or PA consultation. PA consultations are structured around the TTM, to ensure that each construct is covered and that associated POC are applied within the intervention to encourage PA behaviour change. Introducing components from SCT was not relevant to the empirical underpinning of the intervention. The potential for social cognitive variables to predict stage of PA behaviour within the TTM has been explored (Reis et al., 2005); future research may wish to interrogate this. Many models of health behaviour change share constructs and may potentially interact with one another; investigating this was out with the scope and remit of this study and the selected intervention.

Interventions with a theoretical underpinning are reported to be more efficacious than atheoretical approaches (Glanz et al., 2010 and Noar et al., 2007, cited in Stacey et al., 2015). Using a theory-based approach to interventions provides a framework from which to develop and evaluate the intervention and assist in understanding what factors are mediating behaviour change, and why the intervention was successful or otherwise (Stacey et al., 2015). For these reasons, I took an evidence and theory-based approach to my intervention.

Chapter Four: Study Aims and Objectives

'A clear list of objectives will add methodological rigour to a pilot study'

Lancaster et al, 2004: 308

The following articulation of the aim and specific objectives of the study are intended to highlight the main areas of uncertainty to be addressed by the trial and provide a working structure for presenting the methods and results in relation to these objectives (Eldridge et al., 2016).

The aim and objectives of the study were informed by existing research evidence and gaps in the current evidence base (as discussed in Chapter One) and the key reasons for conducting pilot studies (see Chapter Six).

4.1 *Aim*

To evaluate the feasibility and indicative effectiveness of a 6 month RCT of joint PA consultations with CRC-S and their partners.

5.1.1: *Objectives*

1. To evaluate the feasibility of trial and data collection methods by answering the following questions:

a. What is the eligibility rate and what proportion of patients are ineligible and why?
b. What are the consent, recruitment and retention rates to the trial?
c. Is the recruitment strategy feasible and acceptable to participants and recruitment nurses?
d. Is the randomisation procedure and RCT methodology acceptable to participants?
e. Do participants comply with accelerometer data collection and is this a suitable method of PA data collection for CRC-S in a future RCT?

f. What are the completion and attrition rates for key outcome data during the trial?
g. Are self-report outcome measures acceptable and feasible as methods to measure efficacy of the intervention within a definitive trial?
h. Are data collection and monitoring procedures feasible?

2. To evaluate the feasibility and acceptability of the intervention by answering the following questions:

a. Is it feasible and acceptable to conduct at home, face-to-face, joint consultations with CRC-Ss and their partners?
b. Is the content and structure of joint PA consultations suitable for delivery with CRC-Ss and their partners?
c. What are the key elements of joint PA consultations with CRC-Ss and their partners?

3. To evaluate indicative effectiveness of the intervention on key outcome domains by answering the following questions:

a. What is the preliminary impact of joint PA consultations on the PA levels of CRC-Ss and their partners?
b. What is the preliminary impact of joint PA consultations on the mental well-being of CRC-Ss and their partners?
c. What is the preliminary impact of joint PA consultations on the QOL of CRC-Ss and their partners?
d. What is the preliminary impact of joint PA consultations on psychosocial variables aligned with the TTM (SE, POC and DB), in CRC-Ss and their partners?
e. What is the preliminary impact of joint PA consultations on relationship quality and support between CRC-Ss and their partners?

Chapter Five: The Intervention - Joint Physical Activity Consultations

The intervention carried out in this study was joint physical activity (PA) consultations. In this chapter, I will discuss the history of PA consultation and motivational interviewing (MI), which is the delivery method employed in the intervention. I will then present a detailed description of the intervention as it was carried out with CRC-Ss and their partners in this study - including intervention rationale - to ensure transparency and to assist intervention replication in future studies.

The description and justification of the intervention will follow the Template for Intervention Description and Replication (TiDier) Checklist (CONSORT, 2010). TiDier is a tool for reporting details of intervention elements of a study and should be used in conjunction with the CONSORT statement when reporting an intervention in a randomised trial. TiDier is an extension of Item 5 of the CONSORT 2010 Statement (please see Chapter Seven) and as such provides the structure for the latter part of this chapter. Please see the appendices for the TiDier template.

5.1: *History of PA consultation and Motivational Interviewing*

PA consultation was first introduced as exercise consultation by Loughlin and Mutrie (1996). Loughlin and Mutire presented exercise consultation as an alternative to structured, one-to-one exercise programmes in a health promotion setting. Unlike exercise prescription - which prescribes structured exercises to patients or survivors - exercise consultation aims to elicit motivation to change exercise behaviour from the participant and engage them in developing solutions to do so. As discussed in Chapter Three, PA is a distinct concept from exercise; as such, the definition PA consultation reflects this distinction. The principles and structure of the intervention are exactly the same as that of exercise consultation, but the focus is on increasing and maintaining regular PA, during the pursuit of which one might choose to engage in specific exercises to improve or maintain physical fitness and reach their goals.

In accordance with the TTM, PA consultations are tailored at an individual level to match a person's SOC (Marcus et al., 1992). Consultations encourage the

clients to be experts in their own PA behaviour and solutions; it is non-confrontational and non-advice-giving; the client is the expert, not the practitioner (Lewis et al., 2001). PA consultation is a behaviour change intervention underpinned by the TTM and MI techniques; it employs behavioural and cognitive strategies to increase and maintain PA. Consultations take a person-centred or 'guiding' approach. They are not designed to prescribe PA to participants, but rather to consult, listen and motivate participants to make positive PA changes suited to them and their lifestyle. PA consultations address each construct of the TTM (see Chapter Three).

MI originated from work with problem drinkers undertaken by William R. Miller in the late 1980s and early 1990s. In 1991, Miller and Stephen R. Rollnick co-authored the book *Motivational Interviewing: Preparing People to Change Addictive Behaviour.* This book and the MI approach was, similarly to the development of the consultation approach, a response to confrontational and prescriptive practices to behaviour change. Unlike these practices, MI is a directive, non-confrontational, client-centred communication technique that encourages behaviour change by helping clients to explore and work through uncertainty or barriers to changing their behaviour (Emmons and Rollnick, 2001). MI is defined as *a collaborative conversation style for strengthening a person's own motivation and commitment to change* (1991). MI uses empathetic and reflective listening and directive questioning, to help clients focus on uncertainties about behaviour change and overcome them (Lewis et al., 2001).

The TTM and MI complement each other and are frequently associated, although no one theory has ever explicitly linked the two. PA consultation combines the TTM and MI approaches, with the aim of understanding what initiates behaviour change and how this change might occur, whilst adopting an approach which optimises an individual's drive for change (Loughlin and Mutrie, 1995). In other words, within PA consultations, MI facilitates movement through the stages of the TTM for PA behaviour change.

5.2: *Intervention Description*

Item 5 of the CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial - which provided the methodological framework for the

current study (see Chapter Seven) - specifies that when reporting a pilot or feasibility trial, *the interventions for each group should be described with sufficient details to allow replication, including how and when they were actually administered*. Despite this, reporting of interventions is often inadequate or deficient (Hoffmann et al., 2017; Hoffmann et al., 2014). To ensure clarity and transparency, the following intervention description follows the Template for Intervention Description and Replication (TiDier). TiDier was developed and published in 2014 as an extension to Item 5 of the CONSORT checklist, with the aim of assisting authors in the more comprehensive reporting of interventions. My account of the current intervention is structured in line with the TiDier checklist, which can be found in the appendices.

1. *Intervention name*

Joint PA consultation

2. *Why (rationale, theory or goal of the elements essential to the intervention)*

The overall goal of the consultations was to improve participant SOC for PA and to encourage them to meet and maintain the current recommended PA guidelines, as well as reducing sedentary behaviour. The intended outcome of each consultation was to develop a realistic and achievable activity plan that was tailored to participants' lifestyle, motivation (ie. SOC) and health status.

Why PA consultations: I selected PA consultation because previous research has shown effectiveness of TTM-based interventions aimed at improving PA behaviour; please refer to Chapter 3.1.3 and 3.1.4 for discussion of evidence of TTM-based interventions for PA and for behavioural interventions with cancer survivors respectively. Further, PA consultations have been shown to be efficacious at improving the PA and other health outcomes of the general population (van der Bij, 2002; Fitzsimons et al., 2013) and various clinical populations, including patients with type II diabetes (Kirk et al., 2007; Jackson et al., 2007), patients with type I diabetes (Hasler et al., 2000) and those in cardiac rehabilitation (Hughes et al., 2007). Modifiable variables associated with PA behaviour change in colorectal and other cancer populations (see Chapter Two) can be addressed by the constructs of PA consultations, suggesting it to be a

potentially efficacious intervention for this population as well; joint consultations also address those variables associated with social support and shared PA behaviours in couples (see below and Chapter Three).

MI has previously been shown to facilitate positive PA behaviour change in cancer survivors. For example, an RCT of a one-to-one MI intervention with long-term, physically inactive cancer survivors found the use of MI to increase PA at three and six months; further, in the intervention group, those reporting higher SE increased their activity more than those with low SE ($p<0.05$) (Bennett et al., 2007). This not only suggests MI could be an effective method for improving PA in cancer survivors, but that PA consultation - which directly addresses SE – could be an effective and complementary intervention. More recently, qualitative findings by Dennett et al. (2018) found exercise-based cancer rehabilitation that employed MI techniques to elicit increased participation in PA in cancer survivors and a greater sense of personal accountability for PA behaviour.

Although to date PA consultations have not been carried out with cancer survivors, colorectal and other cancer survivors have demonstrated a preference for home-based and face-to-face PA interventions (Brigid et al., 2007; McGowan et al., 2013; Wong et al., 2018). A population-based, cross sectional survey by McGowan et al. (2013), found CRC-Ss reported preferring PA interventions that are home-based, carried out face-to-face and that adopt delivery strategies similar to MI, such as PA counselling. Structured exercise interventions have been shown to be expensive, time consuming and often appealing only to a select group of highly motivated individuals (Kirk et al., 2007). As a result, these sorts of interventions often experience high drop-out rates. MI is a gentle technique with which to approach a population not currently engaging in PA, rather than prescribed exercise; it is more likely to elicit longer term lifestyle behavioural change with this approach (Spencer et al., 2016).

I also selected PA consultations because the intervention applies all four dimensions of the TTM, the importance of which is emphasised by Spencer et al. (2007) and Bridle et al. (2005) for the development and implementation of TTM-based intervention studies aimed at improving PA (see Chapter Three and Figure 5).

Why joint PA consultations: Perceived social support for PA has been linked to increased PA behaviour in cancer survivors (Pinto et al., 2002; Reardon

& Aydin, 1993). Within the context of PA and cancer survivorship, social support refers to, for example, being physically active together with the survivor, encouraging them to be physically active or assisting in carrying out PA (Ungar et al., 2016; Khan et al., 2013). The North Carolina Strategies to Improve Diet, Exercise and Screening Study (NC STRIDES) found social support to be significantly correlated with PA behaviour in CRC-Ss ($p<0.05$)(James et al., 2006). An integrative review of the relationship between psychosocial factors and health behaviour change in cancer survivors also found social support to be important in making adaptive health behaviour changes – particularly PA behaviour change (Park et al., 2007). Further, perceived social support has been shown to facilitate coping with the stressors associated with cancer survivorship (Park et al., 2008; Luszczynska et al., 2005); these coping effects of social support were in turn shown to influence positive health behaviour change amongst 250 cancer survivors in an investigation into cancer survivorship and QOL (Park et al., 2008).

A systematic review by Barber (2012) reported a significant relationship between social support and PA engagement in cancer survivors, in 50% of 22 observational and interventional research studies. The majority of studies in the review focused on social support from family and friends. The sample however, consisted mainly of studies with breast cancer patients; therefore research is needed with other cancer populations, including CRC.

A further quasi-experimental, exploratory study of the effects of social support on PA, self-efficacy (SE) and QOL in cancer survivors and their caregivers found social support to be 'essential to PA participation', in both cancer survivors and their caregivers (Barber, 2013). This suggests that intervention development should consider the active participation of a caregiver alongside the cancer survivor.

This evidence implies a potential role for social support in developing PA interventions for CRC-Ss and a need for intervention development that incorporates social support strategies to increase PA engagement in CRC-Ss. Social support has been shown to improve adherence to PA and is integral to the consultation process (Loughlan and Mutrie,1996); yet, to date, consultations have only been carried out with individuals. This intervention facilitated the potential for social support between CRC-Ss and their partners in promoting PA behaviour change by including partners in the consultation. Partners and spouses provide

an important source of social support (see Chapter Three) and could play a significant role in supporting PA health behaviour change in CRC-Ss. To the best of my knowledge, there are no published couple-based PA intervention studies with CRC-Ss.

There is a gap in the evidence base pertaining to studies using TTM-based interventions for CRC-Ss, despite indications from studies with other cancer survivors suggesting the potential efficacy of such interventions. Further, the barriers to PA most often reported by CRC-Cs could be well addressed by a TTM-based intervention such as PA consultation. PA consultations have never been carried out with CRC-Ss, nor jointly with two people. PA consultation addresses a gap in the evidence base with an intervention that current evidence of TTM-based interventions suggests could be promising with CRC-Ss.

3. *What (materials)*

There were three materials used in the intervention; these were:

Consultation document: A consultation pro-forma was used by the researcher, to guide the structure of the consultation, to ensure that all consultation components were addressed and to take any notes. The consultation pro-forma can be found in the Appendices.

Participant goal sheets: One, three and six month goal sheets were completed during the consultation and left with participants for motivational purposes. Both CRC-Ss and partners were provided with goal sheets at T0 and T1. Goal sheets can be found in the Appendices.

Audio-recorder: An audio-recorder was used to record the consultations, for qualitative analysis and process evaluation purposes.

4. *What (procedures)*

A semi-structured PA consultation format was followed, to ensure all key consultation components were covered (see Appendices for PA consultation pro-

forma). The consultation components address each construct of the TTM for behaviour change (see Chapter Three).

The PA consultation included the following components and discussion points:

- participants' historical and current levels of PA (including SOC) and current PA guidelines
- exploration of the pros and cons of being physically active for each participant (decisional balance)
- exploration of the barriers to PA and how these could be overcome
- exploring activity options and preferences for PA
- exploration of participant SE
- support and motivation
- relapse prevention
- goal setting (to increase and maintain motivation)

The consultation was intended to be informal and relaxed; within the structure, the format covering key consultation components was followed but direction and content within this was in part guided by participants.

The consultations were tailored to each participant's motivational readiness to change and so appropriate POC were employed (see Chapter Three). Table 5 shows how the POC were employed in PA consultations. The primary aim of consultations was to encourage participants to progress towards the current national and ACSM PA guidelines. Participants were supported in developing a realistic and achievable activity plan that was sympathetic to their lifestyle, motivation (ie. SOC) and current health status. Within the activity plan, couples were free to choose their own activities and could choose to exercise together or independently of one another. Couples could also choose if they wanted joint or individual activity plans. A form detailing the short-term (one-month), intermediate (three-month) and long-term (six-month) goals discussed during consultations was left with the participants. Participants were assisted in exploring activity options

and setting goals for themselves that were specific, measurable, acceptable, realistic, time-phased, enjoyable and recordable (SMARTER).

Motivational interviewing skills: A key component of the intervention is that the consultation is client-centred; participants should consider their own reasons for being active and choose their own activity goals (Hughes et al., 2006). Good verbal and non-verbal interpersonal skills were essential to the consultation. The role of the consultant was to motivate participants through the consultation. Key to this was active listening and expressing empathy. Correct non-verbal communication was achieved through, for example, keeping an open posture, leaning towards the participants, use of appropriate eye contact and a relaxed, friendly manner to put participants at ease and convey interest and attention (Hughes et al., 2006). Active listening demonstrated to participants that I was listening carefully and understanding what they were saying. This was achieved by, for example, 'parroting' (ie. repeating back key points that participants discussed) and by paraphrasing (ie. summarising what the participant has said) (Hughes et al., 2006). Empathy showed participants that I was attempting to understand their position and what was going on in their lives. I did this by putting aside my own viewpoints and attempting to see things from their point of view. Empathy can also be achieved through validating participants' perspective, where appropriate (Hughes e tal., 2006).

Essential to the MI, client-centred approach is that the consultant does not talk at or lecture participants, nor try to provide solutions. The consultant should offer suggestions when motivating participants when, for example, trying to overcome barriers to PA. This is best achieved by providing examples of how other individuals have overcome barriers (Loughlan and Mutrie, 1995).

*Table 5: How each POC is addressed during PA consultation**

Process of Change	*PA Consultation Strategy*	*Description of Strategy*
Experiential Processes		
Consciousness raising	Decisional balance table	Providing information about the benefits of PA and discuss the current PA recommendations
Dramatic relief	Decisional balance table	Discussing the risks of inactivity
Environmental reevaluation	Decisional balance table	Emphasise the social and environmental benefits of PA
Self-reevaluation	Review current PA activity status and assess values related to PA	Review current PA activity status and assess values related to PA
Social liberation	Exploring suitable activity options	Raise awareness of potential opportunities to be active and discuss how acceptable and available they are
Behavioural Processes		
Counterconditioning	Exploring suitable activity options	Discussion of how to substitute inactivity for more active options (eg. Taking the stairs instead of the lift)
Helping relationships	Seeking social support	Seeking out friends, family and work colleagues who can provide support
Reinforcement management	Relapse prevention strategies	Rewarding successful attempts at being active
Self-liberation	Goal setting	Making commitments for activity (eg. Goal setting)
Stimulus control	Relapse prevention	Control of situations that may have a negative impact on activity and develop ways to prevent relapse in these situations

**Adapted from Hughes et al. (2006)*

5. *Who provided*

I, in my capacity as doctoral research student, delivered the PA consultations with CRC-Ss and their partners. Prior to the intervention, I attended a PA consultation

and motivational interviewing training course at The University of Stirling, to equip me with the necessary skills to carry out the intervention and to build on my existing health promotion experience. This course was delivered by Dr. Adrienne Hughes, who has specialist knowledge in and has carried out PA consultation. I have also extensively studied health behaviour change and health promotion during my academic career, have worked as a Health Promotion Intern for a bowel cancer charity and remain a health promotion volunteer for that same charity.

6. *How*

The PA consultations were delivered face-to-face and carried out jointly with CRC-Ss *and* their partners.

7. *Where*

The PA consultations were carried out in participants' own homes, in the Greater Glasgow and Clyde area. There was no necessary additional infrastructure for carrying out the consultations. Within the home, consultations were carried out either in the living area or at the dining table, depending on participant preference. The aim was to create a relaxed, non-threatening, friendly atmosphere, in which participants felt comfortable and at ease.

8. *When and how much*

Each couple enrolled in the intervention group received two, joint PA consultations; one at baseline (T0), following collection of baseline data and another three months later (T1). Each consultation was estimated to last between 30 and 45 minutes and varied in length depending on level of engagement by participants.

9. *Tailoring*

Within the structure of the PA consultation, the format covering key consultation components was followed identically for all couples; within this structure,

participants were free to explore each component as it related to them and their lives and so content was in part guided by them. The consultations were tailored to each participant's motivational readiness to change and so appropriate POC were employed (see Chapter Three). Table 5 shows how the POC were employed in PA consultations.

10. *Modifications*

The original protocol for the intervention included carrying out short, follow-up, interim telephone calls with participants after each PA consultation. The purpose of the calls was intended to be discussion of adherence and progress and provision of support. These calls however, were rescinded from the protocol very early on. The reason for this included practical difficulties in arranging the phone calls with both partners; challenges traversing the phone calls with two people and adhering to intervention protocol without introducing an additional component or variable to the intervention by, for example, carrying out the calls individually with each partner.

11. *How well (planned)*

Intervention fidelity was assessed by the researcher, using a PA consultation observer checklist in conjunction with the audio-recording of the intervention. In an attempt to maintain and improve intervention fidelity, audio recordings were assessed as soon as possible after each consultation. Future interventions should aim to have the observer checklist completed by an objective party, during a consultation.

12. *How well (actual)*

The intervention was delivered as planned. Please see Findings, Chapter Eight, for intervention fidelity observational checklist data.

Chapter Six: Study Design and Justification

…clearly defined feasibility objectives and rationale to justify piloting should be provided

- Thabane et al. (2010)

In this chapter, I will discuss the study design I adopted to address the study aim and objectives and my rationale for selecting the research method I used.

The research design selected to address the research aims and objectives and answer the research questions, was a phase II pilot study of a single-centre, prospective, non-blinded, parallel RCT.

My study design was guided by the MRC recommendation that feasibility studies be carried out prior to Phase III clinical or non-pharmacologic trials. Such studies are developmental and adaptive and help to establish modifications that may be required to complex interventions or trial procedures before a large-scale evaluation takes place (https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/).

My study was originally designed as an RCT of joint PA consultations with CRC-Ss and their partners. However, following review of the literature and in-depth discussions with colorectal clinical teams in Lothian and Greater Glasgow and Clyde, and the Beatson West of Scotland In-House Trials Advisory Board (IHTAB) in Glasgow, I modified the study to become a pilot study of the proposed RCT.

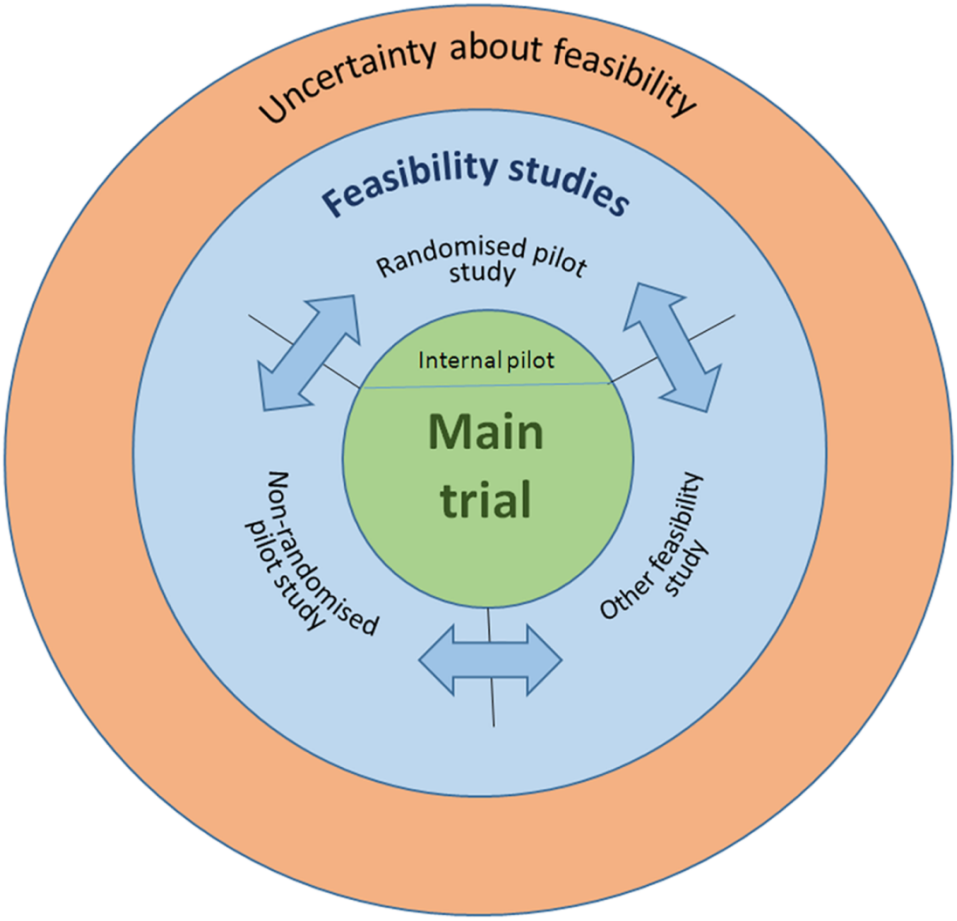
There were numerous reasons for superseding the original RCT with a pilot study. This chapter will first discuss literature on the recommendations for pilot and feasibility studies, which provided background upon which I based this decision. I will then go on to highlight issues of feasibility that directly informed the design of my study. These reasons are presented under the summary headings of the reasons for conducting pilot studies provided by Thabane et al. (2010) and matched to the relevant objectives of the study.

6.1 *Defining feasibility and pilot studies*

The terms ‘feasibility’ and ‘pilot’ study are often used interchangeably to refer to Phase II, preliminary research studies conducted before larger, more definitive RCTs. Eldridge et al. (2016) have developed a conceptual framework for better defining pilot and feasibility studies (see Figure 7). In this framework, the main concept for studies conducted in preparation for an RCT is feasibility. This term can be used to refer to studies that incorporate more than just issues of feasibility within the study (e.g., preliminary indications of outcome). Pilot studies are a subset of feasibility studies and may or may not be randomised. Eldridge et al. recommend that all studies that contribute to the assessment of the feasibility of an RCT evaluating the effect of an intervention be characterised as pilot and/or feasibility, as appropriate (Eldridge et al., 2016). My feasibility study is characterised as a randomised controlled pilot study and will be referred to as such throughout this thesis. Discussion in this section of writing will primarily refer to the overarching concept of feasibility.

Feasibility studies are an important first step in the development of protocols for main RCT studies and may lead to changes in study or intervention design. Intervention description and suggestions for modification, recruitment method assessment and qualitative analysis of study design and intervention are all important contributions that can be made by feasibility studies and used to progress to the next stage of testing. They are a foundational step that avoids wasting time and resources by prematurely progressing to experimental tests of efficacy that are not underpinned by sufficient evidence to suggest potential success (van Teijlingen et al., 2001; Drummond 2017). Feasibility studies are useful for determining early indications of change in the desired outcome, as well as refining the study protocol and working to develop a guide for implementation and replication in an RCT and beyond. The theoretical and/or empirical underpinnings of the intervention and approach serve as the main focus of feasibility studies; claims of efficacy are not normally made in relation to feasibility outcome results (see below).

Figure 7: *Conceptual Framework (Eldridge et al., 2016)*



The Medical Research Council (MRC) Guidance for Developing and Evaluating Complex Interventions (Craig, Deippe, Macintyre, Michie, Nazareth and Petticrew, 2008, on behalf of the MRC) highlights the importance of assessing feasibility and piloting methods in preparation for RCTs, to anticipate such issues as acceptability, compliance, delivery of the intervention and recruitment and retention. They also recommend the use of quantitative and qualitative methods when assessing feasibility (www.mrc.ac.uk/complexintervetnionguidance).

Historically, feasibility studies have not been as valued or published as much as RCTs and other intervention studies. More recently however, feasibility studies have gained increasing recognition and there is now a journal dedicated to feasibility and pilot study research (*Pilot and Feasibility Studies*).

6.2: *Pilot studies and efficacy testing*

As discussed, feasibility studies are carried out when there is a theoretical and empirical motivation for an intervention but a full-scale trial cannot be justified due to too many unknown factors surrounding the study. Feasibility studies are used to assess the feasibility of an intervention and trial procedures and can indicate impact of the intervention on selected outcomes. The endpoints for a feasibility study are *not* the same as those for the main study; the endpoints for a feasibility study are outcome variables that affect successful trial outcome and not measures of intervention efficacy (Moore, 2011). Feasibility studies, however, frequently include sample size calculation for a larger main study as an objective of research. Estimation of between group effect sizes are often carried out in feasibility studies of RCTs, with the purpose of informing study design and sample size in a full scale, hypothesis testing RCT (e.g., Grimmett et al., 2015). However, the appropriateness and relevance of sample size calculation as an objective in feasibility studies has been strongly contested, as such studies are not sufficiently powered to draw definitive conclusions about intervention efficacy and therefore sample size estimation (Leon et al., 2011; Lancaster et al., 2004; van Tejilingen et al., 2001; Thabane et al. 2010). Fey and Finestack (2009) describe a pilot study as a small scale version of the main study, which is primarily exploratory and preliminary with respect to intervention outcomes. Pilot studies can give early indications of the presence of efficacy but given their smaller sample sizes are not normally powered to detect clinically or statistically meaningful effects (Fey and Finestack, 2009). This is supported by Arain et al., (2010), who discuss that pilot studies should mainly be descriptive because hypothesis testing requires a powered sample size which pilot studies do not have. Leon et al. (2011) also state that pilot studies are not designed to test hypothesis and as such should not carry out inferential statistics. This in turn precludes any significance testing on data. Leon et al. (2011) argue that although pilot studies involve measures of outcome they should *not* be viewed as a preliminary test of intervention hypotheses for two reasons. First, due to lack of evidence pertaining to methodology and the intervention with the study population and secondly, due to small sample size. Further, feasibility studies serve as a means of finding and amending problems with the research design so that an improved design can be tested in the main study. As Kraemer et al. (2006) highlight, these amendments to study design call into question whether the effect size estimates originating from feasibility studies

are reflective of true effect size in the main study. Modifications made in light of the findings of a feasibility study could impact on the accuracy of data. Thabane et al. (2010) reinforce this difficulty inherent in extrapolating from pilot study data. If pilot study methodology or the intervention is revised before a main study, then outcome data from the pilot study is based on a different study from the one trialled in the main study. Any variance estimates or sample size calculations would therefore be rendered invalid. Both Kraemer et al. and Thabane et al. recommend that feasibility studies not be used for determining treatment effects or variance estimates for sample size calculations (Thabane et al., 2010).

An RCT carried out by Pinto et al. (2013) demonstrates the need for appropriate feasibility research before RCTs are undertaken and the caution with which significance testing should be carried out in feasibility studies. Pinto et al. trialled a home-based PA intervention (telephone counselling to support PA) with CRC-Ss. In total, 46 participants were randomised to the study and results indicated 'significant' increases in minutes of PA and caloric expenditure at 3 months ($p=0.021$), as well as 'significant' improvements in fitness at 3, 6 and 12 months ($p=0.017$) compared to the control group (Pinto et al., 2013). However, the study did not meet the required sample size of 134 participants, due to recruitment issues; consequently the study did not have statistical power. The significance of the outcome results are therefore uncertain. Had the study carried out the necessary feasibility work prior to the trial, recruitment problems – and therefore ethically dubious randomisation of participants and wasting of time and resources – could have been avoided.

A feasibility study carried out by Grimmett et al. (2015) also highlights the caution with which feasibility studies that have carried out inferential statistics should be interpreted. Grimmett et al. recruited 29 CRC-Ss to a non-randomised diet and PA intervention study. The main aims of the study were to assess feasibility and acceptability and provide an 'indication' of behavioural impact. Of the 29 participants, 23 completed the trial (18 with full compliance). Grimmett et al. discuss observing 'significant' improvements in activity ($p=0.004$) as well as 'clinically meaningful' improvement in QOL ($p=0.001$). However, effect size is one of the most important indicators of statistical and clinical significance (Page, 2014); the study had a very small sample size and therefore – and as acknowledged by the authors – limited power. Further, as there was no control group, it is

impossible to indicate whether or not any positive outcomes occurred due to the intervention. This reinforces that feasibility studies should not go beyond the remit of the data.

Anderson et al. (2010) demonstrate the importance of feasibility studies and indeed contributed to the rationale for carrying out this study (see Chapter Two). However, with a sample size of 28, Anderson et al. carried out significance testing on outcome results. These results should be interpreted with caution and not be extrapolated alone to trial development in this area. Instead, results such as these provide a building block upon which to continue feasibility work and progress towards a definitive RCT.

As will be discussed further in the methodology, having carefully reviewed the evidence and by identifying the limitations of previous research, it was not an objective of this study to detect significant differences in effect size using inferential statistical testing. My sample size was based on the pragmatics of recruitment and feasibility objectives of the study. The purpose of my study is to develop hypotheses, not to test them. Significance testing and reporting of effect size in feasibility studies goes beyond the scope and remit of the data. As Sudman (1976) advise:

> *Samples consisting of 20-50 participants are most appropriate during the early stages of research design, when developing hypotheses and the procedures for measuring them.*
>
> Sudman, 1976

6.3: Feasibility concerns of current study

Process:

Process is defined by Thabane et al. (2010) as that which assesses the feasibility of the processes key to the success of the main study. I sought to assess the feasibility of the following processes:

Eligibility, recruitment and retention (Objectives 1a-c): As previously discussed, there was insufficient evidence upon which to base the design of a full

RCT. Evidence of the feasibility of the steps necessary to carry out a full trial, including likely recruitment rates, retention to the trial and intervention feasibility, were unavailable. For example, I did not know if the eligibility criteria were appropriate or overly restrictive or if participants were likely to comply with or adhere to study procedures. Further, I was uncertain as to whether or not CRC-Ss and their partners would be willing and able to take part in a PA intervention trial. Discussions with the IHTAB and colorectal clinical teams raised concerns about the feasibility of recruiting CRC-Ss to the study. They were concerned that the average age of the target population would be a barrier to recruitment. As discussed in Chapter One, 72% of CRC cases are diagnosed in people aged 65 years and over, and the average age of diagnosis is 71 years (Cancer Research UK,). Recruitment of older adults to PA intervention studies has been shown to be poor (Harris et al., 2008; Halbert et al., 1999). The clinical teams felt that this patient group would be unlikely to be motivated to participate in a PA intervention study, and that many would be unable to given their age. Given the lack of previous research evidence to demonstrate the potential to recruit CRC-Ss to behaviour change intervention studies, a pilot study was more appropriate to address the feasibility of recruitment of CRC-Ss to the study. Further, it is unethical to embark on a full scale trial when uncertain of the ability of the study to recruit participants and meet recruitment targets (Halpern et al., 2002).

Despite the concerns of the IHTAB, the Board were very supportive of the study. They recommended that the trial be adapted to a pilot study and incorporate feasibility measures of recruiting for and conducting the intervention with CRC-Ss and their partners into the study design.

Recruitment and consent (Objectives 1b-c): It is important to establish the likely consent rate for patients entering a larger trial (Ross-McGill et al. 2000; Burrows et al. 2001 in Lancaster et al., 2004). Given that there have been few RCTs of PA interventions carried out with CRC-Ss, and none to date recruiting CRC-Ss and their partners, determining consent rates in a feasibility study was necessary before proceeding to a larger trial. Barriers in recruitment to a trial should be carefully researched and piloted (Ross et al, 1999). Inability to recruit participants to a trial will reduce statistical power, risk the early cessation of the trial and have major funding implications.

Randomisation procedure (Objective 1d): Pilot studies can be randomised or not (Thabane et al., 2010). I conducted a randomised pilot study for two reasons. Firstly, it permitted me to assess the feasibility of my chosen method of randomisation and the acceptability of the concept and process of randomisation to participants. My primary aim was to assess the feasibility of the study protocol for an RCT of my intervention; this included the acceptability of randomisation to CRC-Ss and their partners. Secondly, although the study was not powered to detect any statistically significant effects of the intervention on study outcomes (see Chapter Seven), having a control group permitted preliminary assessment of any differences in change in outcome results over time, between those who received PA consultations and those who did not.

Suitability of proposed primary outcome for definitive RCT (Objective 1e): Given the lack of previous research, PA measured objectively using accelerometer data as the primary outcome measure was not justified, because I was uncertain of the reliability of the outcome and of the feasibility of measurement with CRC-Ss. I needed to conduct a pilot study to determine the suitability of accelerometery as a primary outcome measure with the target population. As Lancaster et al., (2010) assert, a measure should only be used as a primary outcome if it has been shown to be valid and reliable in the population in which it is intended for use before it's use in a main study; a pilot study permits this (Lancaster et al., 2010). The acceptability of accelerometers to participants and whether or not they would comply with wearing them was also unknown. During the trial, participants would be asked to wear accelerometers on a belt around their waist during waking hours for 7 days on three separate occasions over 6 months. The majority of participants were likely to be over the age of 65 and a number of them may have a stoma. Assessing the feasibility of the use of accelerometers in an RCT with CRC-Ss was therefore a necessary objective of a pilot study that must be established before a full-scale trial incorporating this outcome measure.

Testing data collection questionnaires (Objective 1f-g): As part of data collection, participants were asked to self-complete a booklet of questionnaires (GSE, HADS, FCRI, POC, IPAQ) at 3 time points during the study. I wanted to investigate the appropriateness of the booklet and each of the questionnaires, assess completion rates and potential burden to participants and to establish any barriers to completion of the instruments. Piloting of data collection and follow-up

forms is recommended before a full study, especially if self-completion is required by participants (Lancaster et al., 2010).

Resources:

(*Objective 1h*) Resources are defined by Thabane et al. (2010) as that which assesses time and resource problems that can occur during the main study. There were numerous possible time and resource issues that may arise during the study, which should be established in a pilot study before embarking on a main study. I was specifically interested in the length of time it would take to program the accelerometers and download the data and how long it would take to fill out questionnaires and to process them. Another important resource consideration was how much time would be required of colorectal nurses to recruit participants. It is the purpose of a pilot study to collect pilot data on these integral resource considerations.

Management:

Recruitment (*Objective 1c):* Management is defined by Thabane et al. (2010) as covering potential human and data management problems. I was specifically concerned with staff and data management problems at the recruitment site. I was unsure if the method of identifying participants would be feasible or if the nursing staff would adhere to the guidance I provided with regards to screening and recruiting potential participants. I needed to investigate what challenges the protocol presented for the nursing staff and the site recruiting for the study. This might include identifying eligible patients, recording patient data and informing potential participants about the study.

Assessment of the proposed recruitment procedures and likelihood of successful recruitment and consent to participate was an integral part of the feasibility of this study. Any practical problems in the identification and recruitment of patients and their partners to the trial needed to be established before the recruitment strategy can be exercised in a larger study.

Scientific:

Scientific considerations as defined by Thabane et al. (2010) include, where applicable, the assessment of treatment safety, dose, response, effect and variance of effect. The scientific considerations were as follows:

Sample size (Objective 1a): A further reason for developing the pilot study was the lack of sufficient and applicable evidence upon which to estimate the effect size for a full trial of PA consultations with CRC-Ss. Again, this was a concern that was also raised by the IHTAB. There was no available power calculation for an RCT of PA consultations, using accelerometer data as the primary outcome measure, with a CRC population (as discussed in Chapter One). The sample size for the original trial was based on an RCT of PA consultations with Type II diabetes patients, who had an average age of 57 years. This data was not relevant to a colorectal cancer population, with a much older average age and a very different medical condition. Due to there being insufficient evidence as to the efficacy of PA interventions with CRC-Ss, I designed my study to search for possible effects or associations resulting from PA consultations that might be worth pursuing in a larger study. The aim of the study was not to estimate the effect of the intervention – as there was inadequate power to assess statistical significance - but to investigate any positive changes in outcome measures that may have resulted from the intervention and therefore provide a platform for a larger, more definitive trial of PA consultations with CRC-Ss. Determining preliminary data for the primary outcome measure that may contribute to sample size calculation in a larger trial is often an important reason for conducting a pilot study (Lancaster et al., 2004).

However, the pilot was also testing the feasibility of the content and delivery of the intervention as well as of the study protocol. Therefore, estimates of mean and standard deviation to inform sample size calculation would have to be used with caution, especially if modifications to the intervention were recommended for a future study. Further, due to the relative small sample size of each arm of the study caution would have to be taken in any estimation of parameters. After sample division into sample intervention and control arms, and division of CRC-S and partner, each analysis group would contain a maximum of 15 participants.

Acceptability of the intervention (Objectives 2a-c): The feasibility of conducting PA consultations jointly with CRC-Ss and their partners was unknown

and therefore also informed the design of my pilot study. Whilst PA consultations are an established intervention with other patient groups (for example, diabetes and coronary heart disease), the acceptability and potential efficacy of this intervention with CRC-Ss or with couples has never been studied. Further, I modified an existing intervention which I then sought to assess during the course of the study. Possible alteration and development of the intervention was an anticipated outcome of the research. Therefore, a pilot study was more relevant to the iterative nature of my intervention and study objectives.

The intervention I trialled in the study was PA consultations, conducted jointly with CRC-Ss and their partners. As discussed in Chapter Five, PA consultations have been shown to be effective at improving PA levels in other clinical populations - such as CHD and type II diabetes – and in the general population. However, home-based, face-to-face PA consultations have never been carried out with CRC-Ss or with two people simultaneously. Therefore, in addition to the feasibility assessment of study protocol and RCT methodology, the intervention was also assessed for feasibility (see Chapter 7). Firstly, the feasibility of applying a dyadic approach to an intervention intended for use with individuals was uncertain. I wanted to develop and test the components of the intervention and the practicability of its implementation and delivery. For example, administration of dyadic PA consultations, the appropriateness of using the consultation with couples in its current format and the time taken to carry out the consultations had to be considered. Consultations are patient-centred and tailored to an individual's motivational readiness for change (see Chapter Five). Joint consultations therefore presented a challenge, as participants may be at different stages of change. How the consultations would work in practice was uncertain. However, literature suggests that couples often share health behaviours (see Chapter Three), therefore the assumption was that most couples would be at a similar SOC.

Secondly, I aimed to assess the acceptability of other core components of the intervention. This included the content and delivery of PA consultations to participants. In particular, I sought to evaluate the format that the consultations take and its malleability for use with two people. The PA consultation guide can be found in the Appendices. I wanted to assess how this would work with couples

and if extracting the PA goal component and developing a goal sheet might be a useful tool in the intervention.

Thus, the study was an iterative process, including the development of the intervention. Along with study protocol, the PA consultations were also being assessed for feasibility. This permits any necessary modifications of the intervention to make it feasible for use in a larger study. For example, the original study protocol included telephone catch-up calls in between consultations for those in the intervention group. The purpose of the calls was to discuss how participants were getting on with their PA goals and to provide additional motivation. However, early on during the course of the study, these calls were rescinded from the intervention. It was difficult to arrange the calls with participants and given that the consultations took place with both partners, carrying out calls individually was incongruous, time-consuming and difficult to coordinate.

I thus designed my pilot study with the aim of informing the development of a future, full-scale randomised controlled trial of PA consultations with CRC-Ss and their partners. I concluded that launching a full-scale trial without sufficient confidence in the potential to recruit and retain participants, or in the practicalities of carrying out joint PA consultations, would be unethical. An exploratory pilot study investigating RCT and intervention feasibility was therefore developed.

Chapter Seven: Methodology - Pilot Study RCT

7.1: *Introduction*

In this chapter I will describe the methods I used to conduct my pilot study. As my pilot study involved carrying out an RCT of a behavioural intervention, I wanted to follow the Consolidated Standards for Reporting Trials (CONSORT) guidelines for reporting trials of non-pharmacological treatments (CONSORT, 2010). The CONSORT statement is a guideline that aims to improve the reporting of randomised trials; the guidelines seek to ensure that randomised trial design, conduct, analysis and interpretation are presented transparently for readers to understand and to assess the validity of study results (Schultz et al., 2010). The current CONSORT guidelines however, do not include items pertaining to the reporting pilot and feasibility trials. Therefore, the framework I used to report my trial is the 2010 CONSORT statement extension to randomised pilot and feasibility trials, as presented by Eldridge et al. (2016). This framework – published towards the end of my study - has extended the CONSORT guidelines to make the information provided by and interpretation of each item pertinent to pilot and feasibility trials. The guidelines provide a 26-item checklist for reporting these trials, a separate checklist for the abstract and a template for a CONSORT flow diagram for pilot and feasibility trials. Completed checklists for this study can be found in the Appendices; the flow diagram is presented and discussed in Chapter Eight. Note: I have followed the sections of the Eldridge et al. (2016) framework sequentially in writing up this study and RCT; the item numbers appear as they correspond to the chapters in my thesis, rather than as they are numbered in the checklist.

I will begin by describing the participants and setting for the study, including recruitment and data collection procedures. I will then go on to describe sample specification and eligibility criteria for participants before intervention procedure. I will then define the primary and secondary outcomes measured, including how and when they were assessed. How the sample size was determined will be discussed, followed by the method of randomisation, allocation concealment and implementation in place during the study. I will then review blinding during the trial. Data analysis methods used to assess feasibility and to compare groups for

change in trial outcomes over time will then be reported. I will then go on to describe and justify the analytical method adopted in the embedded qualitative portion of the study. Finally, ethical considerations will be reviewed.

This chapter will elicit as far as possible complete and transparent information on trial methodology.

7.2*: Trial design*

7.2.1: This was a phase II pilot study of a single-centre, prospective, non-blinded, parallel randomised controlled trial.

7.2.2: *Eligibility criteria*

Participant inclusion and exclusion criteria are presented in Table 6. Initially, the eligibility criteria included CRC-Ss who were 6-30 months since diagnosis at the point of recruitment. However, I amended the protocol to include CRC-Ss who had completed surgery in the previous 30 months (January 2009 – August 2011) as eligible for participation in the study. Following discussion with the clinical team at the recruitment site, months since surgery was selected for two reasons. Firstly, because time since surgery would elucidate more accurately the most appropriate and effective time to introduce a PA behaviour intervention with CRC-Ss. To be eligible for inclusion in the study, participants must have completed all surgery and treatment for CRC; by including only those diagnosed in the last 6-32 months, those who have received a diagnosis and completed all surgery and treatment for colorectal cancer in the past 6 months would be unreasonably excluded. A cancer diagnosis has been shown to be a 'teachable moment' at which survivors are motivated to change their health behaviours (Demark-Wahnefried et al., 2006). Patients who receive a diagnosis of CRC receive surgery within a maximum of 4-6 weeks, regardless of the stage of the cancer. Therefore, patients who have completed surgery in the past 32 months may be disposed to PA behaviour change.

Table 6: *Eligibility criteria*

	Inclusion criteria	**Exclusion criteria**
Colorectal Cancer Survivor (CRC-S)	(i) Initial diagnosis Dukes stage A-C2 colorectal cancer with no current evidence of metastatic disease (ii) Have completed surgery and/or treatment in the past 32 months (iii) Is not currently undergoing adjuvant chemotherapy and/or radiation therapy for cancer (iv) ≥ 18 years of age (v) Has a partner (vi) Is not currently meeting national physical activity guidelines (of 30 minutes moderate-intensity activity five times per week) (vii) Able to communicate in English	(i) Initial diagnosis Dukes stage D (ii) Evidence of metastatic disease (iii) Is currently undergoing surgery or adjuvant chemotherapy and/or radiation therapy for cancer (iv) Suffers from unstable cardiac or respiratory disease (due to inappropriateness of PA intervention) (iv) Partner is unwilling to participate in study (vi) Is currently achieving national physical activity guidelines (vii) Unable to communicate in English
Partner	(i) Partner of individual living with colorectal cancer included in the study (ii) ≥ 18 years of age (iii) Is not currently undergoing surgery or adjuvant chemotherapy and/or radiation therapy for cancer (vi) Able to communicate in English	(i) Is currently undergoing surgery or adjuvant chemotherapy and/or radiation therapy for cancer (ii) Suffers from unstable cardiac or respiratory disease (due to inappropriateness of physical activity intervention) (iii) Unable to communicate in English.

Months since surgery was also defined in the inclusion criteria for patients for pragmatic reasons. For recruitment purposes, it is more practical and efficient for nursing staff to apply this criterion to patient records when screening for eligibility for the study.

Following the recommendation of the clinical team at the research site, only patients who had completed all surgery and treatment for CRC were eligible for

the study, as they perceived that approaching very poorly patients in the middle of their treatment to take part in a PA intervention was not appropriate. They perceived that patients in the middle of treatment would not have been physically able to take part. This is supported by findings of a recent meta-analysis of PA in cancer patients and survivors (Schrack et al., 2017).

Following review of the literature and recommendations from CRC clinicians, patients with a diagnosis of Dukes Stage D CRC were excluded because the cancer is too advanced for participation in the study. In general, patients diagnosed with Dukes Stage D have metastatic disease where the cancer has spread to their lymph nodes and other parts of the body, most commonly the liver and the lungs. Therefore, only patients diagnosed with Dukes Stage A-C2 colorectal cancer were eligible for inclusion in the study.

Only CRC-Ss with partners were included in the study. This was because, as discussed in Chapters Two and Three, couples have been shown to share similar lifestyles and health behaviours and to directly impact on one another's habits and choices. Partners of CRC-Ss could support the CRC-S in increasing their PA level and also potentially improve their own health outcomes. Blood relatives were excluded due to the added variable of real or perceived genetic familial risk. Although genetics are a relatively small risk factor in the development of CRC (www.cancer.org), a diagnosis within a family may impact on the perceived risk of other family members and influence the outcomes of the study (Stark et al., 2006).

The decision to include only partners in the study however, was an important feasibility matter to be addressed in the pilot. Only including people with partners may drastically reduce the eligible population from which to draw the study sample. Not everyone has a partner. Further, excluding otherwise eligible CRC-Ss who could benefit from the intervention and who may have other family members or friends who would be willing and able to participate and may themselves be eligible for and benefit from the study, could be viewed as unethical and unnecessary. This issue is addressed in feasibility analysis (see Chapters Eight and Nine).

The accuracy of pilot study results is uncertain when unrepresentative samples are used (Johanson and Brooks, 2010), therefore determining whether or not the eligibility criteria in this study is appropriate or too restrictive and whether

or not the resulting sample is representative of the wider population, was an important feasibility outcome of the study.

7.2.3: *Setting*

This was a single-site pilot study; all participants were recruited from NHS Gartnavel General Hospital in Glasgow (NHS Greater Glasgow and Clyde). Data was collected from participants in their own home.

7.2.4: *Recruitment*

Consultant clinical lists of patients who received a diagnosis of colorectal cancer were screened by two colorectal nurses at the hospital to identify patients who were eligible for participation in the study. To ensure that participation was entirely voluntary and not influenced by the researcher, potential participants first had to consent to be contacted about the study before I initiated any communication. The colorectal nurses telephoned eligible participants to inform them about the study and request this consent. The nurses were provided with a participant information sheet for reference and a pro-forma for assessing patient SOC. If a patient consented to be contacted about the study, I posted them a participant information pack, which included a covering letter and participant information sheet. I then received the name and telephone number (no clinical information at this stage) of consenting participants from the nurses. Only the names and contact details of potential participants who consented to be contacted were passed on to me by the nurses. A week later, I then telephoned patients who consented to be contacted to discuss the study and to give verbal consent to participate. They were asked to provide details of their partners' eligibility to take part in the study and when and by what telephone number it was best to contact the partner if they were unavailable at that time. I then telephoned the partner to discuss the study and to obtain verbal consent to participate. If the partner declined to take part, the couple were withdrawn from the study.

During telephone conversations, potential participants were given the opportunity to ask any questions about the study and to discuss any concerns. It was reiterated to participants that they we not in any way obligated to take part

and that the decision was entirely voluntary. I also emphasised that, should participants decide to take part, they were free to withdraw from the study at any time.

If both partners consented to take part in the study, I arranged a suitable date and time with them to visit their home, where I would obtain written consent and collect baseline data. It was again made clear to participants that arranging the visit did not obligate them to take part in the study and that they could still opt-out if they reconsidered their participation.

At the initial home visit, I obtained the written consent of both partners and collected baseline data.

Recruitment was defined as taking place if couples withdrew after written consent but *before* randomisation. If a couple consented in writing to take part in the study but dropped out before they were randomised to intervention or control group, another eligible patient was contacted to request permission to be contacted by the researcher about the study. There was no further recruitment of couples to replace those who dropped-out after randomisation. If the patient or partner withdrew, then the couple were withdrawn from the study.

7.2.5: *Intervention:*

The intervention for this study was joint PA consultations. Please refer to Chapter Five for a detailed description and discussion of the intervention, which will allow for replication. The PA consultations were intended to improve participant SOC and to encourage them to meet and maintain current recommended PA guidelines and reduce sedentary behaviour. Participants were randomised to either the intervention or the control group:

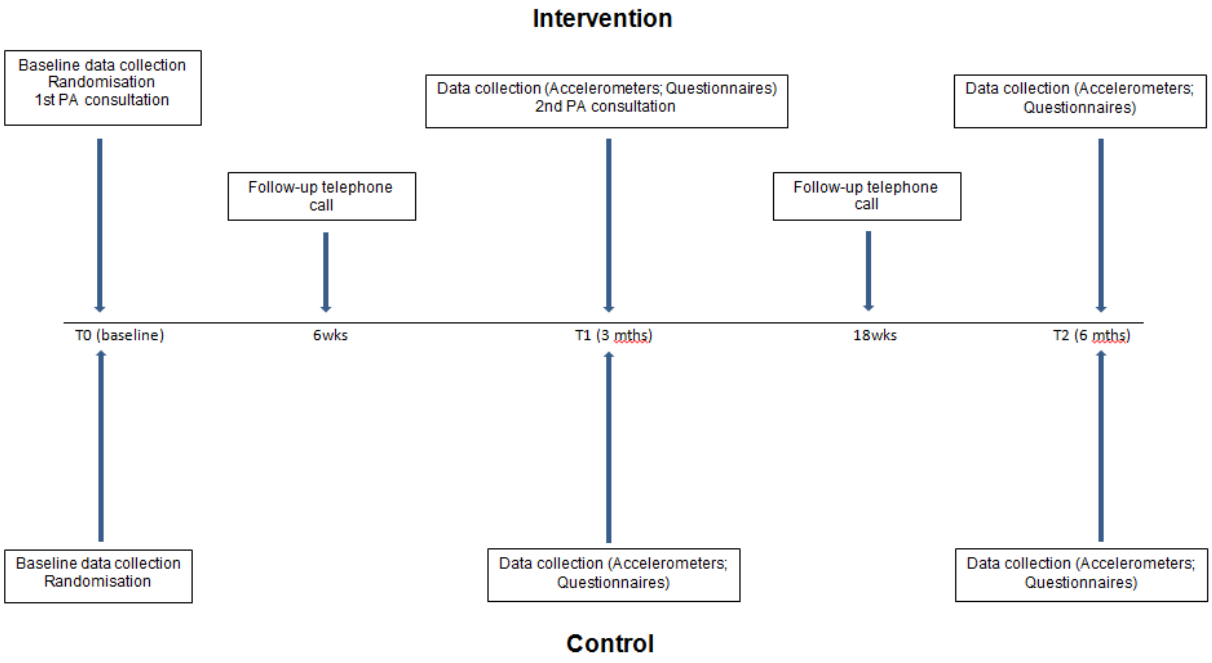
Intervention group: Couples in the intervention group received one home-based, face-to-face PA consultation after collection of baseline measures and a further consultation three months later and after T1 data collection. It was also in the study protocol that couples would receive contact telephone calls from the researcher following each consultation; one at six weeks and one at 16 weeks (two in total throughout their participation in the study). The purposes of the telephone call were to follow-up with participants and discuss any challenges they might be facing in achieving their goals. It was anticipated that the face-to-face PA

consultations would last between 30 minutes and an hour. All PA consultations were audio-recorded, where permitted by participants to do so. The purpose of recording the consultations was to review for content and process evaluation and to assess intervention fidelity and development.

Control group: Couples randomised to Group Two received usual care. This involved follow up appointments at the hospital clinic to detect any evidence of cancer recurrence. Group 2 did not receive any advice on PA.

All participants were enrolled in the study for a total of 6 months. Figure 8 presents a timeline of participants' enrolment in the study, including time points for PA consultations and outcome measure assessments. This will also assist in the replication of the intervention.

Figure 8: Intervention Timeline



7.2.6*: Data collection methods*

A pilot study is an evaluation of the feasibility of the proposed intervention and study procedures and, in this case, an RCT of that intervention. Therefore, methods ordinarily adopted in the post-hoc evaluation of an RCT were interwoven into this study. I used a mixed-method approach to data collection, to address

feasibility objectives and key outcome domains of the intervention. I used quantitative and qualitative techniques, including: accelerometers; trial questionnaire booklets; bio-impedance monitoring; post-trial evaluation questionnaires; a semi-structured interview with the recruitment nurses and a post-hoc evaluation of consultation recordings using observer checklists, to determine intervention fidelity and internal validity of the intervention and to inform feasibility. Further, I carried out a situational analysis of the consultations in order to provide depth to feasibility assessment and to map the possible mechanisms through which dyadic PA consultations might function.

Initially – and detailed in my study protocol - telephone interviews were to be carried out with a number of participants in both the intervention and control arms of the study. However, although evaluation questionnaire return was high, opt-in to telephone interviews was low. Given this and because I felt that burden on participants during the study was already high, I made the decision to rescind telephone interviews from the study.

Accelerometers: Accelerometers are motion sensors that record acceleration over a given time and therefore permit assessment of frequency, intensity and duration of PA through body movement (Ridgers et al., 2011). Accelerometers have been shown to be a valid and reliable objective measure of PA and sedentary behaviour (Murphy, 2009; Hendelmen et al., 2000; Welk, 2002). Recent reviews also conclude that Actigraph accelerometers specifically provide an objective, practical, accurate, and reliable method of measuring exercise without influencing behaviour (Reilly et al., 2008) and they have been used to assess PA in a number of research studies (Hughes et al., 2007; Anderson et al., 2010).
Accelerometers are valid for measuring most types of PA (Melanson et al., 1995), however, activities that expend energy without a proportional increase in body acceleration – such as walking uphill – and those that require a lot of upper body movement, are not detected as accurately (Hughes et al., 2006). Further, until the use of accelerometry in clinical trials is more established and further validated, it is recommended that self-report measures of PA should be administered as part of PA assessment (Napolitano et al., 2010; Schutz et al., 2001).

Physical activity was measured objectively using the Actigraph GT3X+ triaxial accelerometer (Actigraph LLC, Pensacola, Florida). The Actigraph GT3X+ detects movement on 3 planes and has been shown to be effective in accurately measuring free-living activity (McMinn et al., 2013).

Questionnaire booklet: At baseline, 3 and 6 month time points, participants were given a questionnaire booklet to complete. The booklet contained a range of quantitative data collection instruments to measure key intervention outcomes (detailed below). The questionnaire booklets can be found in the Appendices.

Bio-impedance monitor: At baseline, 3 and 6 month time points, body composition (ie. fat and lean mass) was estimated using a portable foot-to-foot bioelectrical impedance monitor (Tanita TBF300 MA Body Composition Analyser, Harlow Printing Ltd, Tyne and Wear). There is good agreement between bio impedance and criterion methods for estimating fat mass and changes in body composition during weight loss in adults (Heyward et al., 1996). Unfortunately, due to my own error, data for this outcome was lost and is therefore not reported as part of the pilot study.

Post-trial evaluation questionnaires: Following trial completion, each participant was posted a structured study evaluation questionnaire. The questionnaire asked about recruitment to the study and group allocation, outcome measures, experience during the study, overall satisfaction and time since study participation. Answers were given on a Likert scale, ranging from one – 'strongly disagree', to two – 'strongly agree'. There was also space for participants to add any additional comments.

Participants were posted evaluation questionnaires in order to achieve valid information that was not influenced by the presence of the researcher. Evaluation forms were tailored to intervention and control groups and to CRC-Ss and partners, and can be found in the Appendices.

When constructing the questionnaire, I ensured as far as possible that the wording of the questions was direct, clear and would be meaningful to participants; that question rating scales were clearly defined; that questions were not biased or making any assumptions; that the data obtained would be manageable for analysis and that the questionnaire itself was short and succinct yet focused and pertaining directly to the research objectives (so as to minimise burden on participants).

Semi-structured interview:

I carried out a joint, semi-structured qualitative interview with the two colorectal nurses who recruited for the study. The purpose of the interview was to inform feasibility assessment of recruitment methods and eligibility criteria. The nurses were asked about their experiences of recruiting for the study, any barriers they faced, how much of their time the recruitment process demanded, trial procedures and the intervention.

Audio recordings of PA consultations:

Intervention fidelity: Intervention fidelity was assessed using audio-recordings of the PA consultations. Where permitted, PA consultations were audio-recorded and later evaluated for consistency of delivery and content using a PA consultation observer checklist (see Chapter Eight). These recordings and checklists were integral to assessing study feasibility objectives.

Situational Analysis: Situational Analysis was carried out on the audio-recordings of the PA consultations, to inform feasibility assessment and the process of implementation. The audio-recordings were transcribed intelligent-verbatim and messy-maps produced using the transcripts and the recordings. From the messy maps, I then created an Ordered Situational Map of the consultations using the headings for Ordered Situational Maps by Clake (2005) (see Chapter Eight).

7.2.7: *Outcomes*

Objective 1

a)In order to address objective 1a, I recorded the total number of patients screened for participation in the study, how many were deemed ineligible and the reason(s) why each one was excluded.

Recruitment nurses were also asked to seek consent to record anonymous demographic and clinical data on the following, from patients identified as eligible who did and did not consent to be contacted about the study:

- Age
- Sex
- Postcode
- Stage of cancer
- Location of cancer
- Stoma
- Date of surgery/completion of treatment

This information was recorded in order to further assess how representative the final sample recruited to the study was of the wider patient population. No further contact was made with those who decided not to participate.

The eligibility rate was calculated by dividing the number of people who underwent treatment for CRC in the previous 30 months (ie. the number of people screened) by the number who met the inclusion criteria. Nurses recorded why patients were excluded on a screening and recruitment form.

Recruitment nurses were asked about eligibility criteria during their interview (see Appendices).

Demographics: I collected demographic information on each of the participants via questionnaire, including age, gender, highest level of education, current employment status, household income and health co-morbidities. Information on stage of cancer, presence of stoma and treatment was recorded by nurses during recruitment. I collected this information in order to assess if the sample was representative of the wider study population. Further, these variables may be of interest in a future trial assessing correlation between these variables and trial outcomes.

b) In order to address objective 1b, consent rate was calculated by dividing the number of eligible patients contacted by recruitment nurses about the study with those who consented in writing to take part. Nurses recorded reasons given for not consenting to be contacted by the researcher and I recorded reasons given not to participate in the study following contact with those who did consent to be contacted about the study.

I kept a record of the total number of weeks required to meet the sample size to inform recruitment feasibility.

The number of participants enrolled and the number of participants who completed the trial were compared to determine retention.

c) In order to determine the feasibility of the recruitment strategy and therefore answer research objective 1c, I carried out a joint, semi-structured qualitative interview with the two colorectal nurses who recruited for the study. The purpose of the interview was to inform feasibility assessment of recruitment methods and eligibility criteria. The nurses were asked about their experience of recruiting for the study, any barriers they faced, how much of their time the recruitment process demanded, trial procedures and the intervention. The interview topic guide can be found in the Appendices.

Questions on experience and perceived feasibility of the recruitment method were included in the interview (please see interview schedule, Appendices).

Participants who enrolled in the trial were also asked about their experience and views of the recruitment process in the post-study questionnaire (see Appendices).

d) In order to assess the acceptability of RCT methodology to participants, this topic was covered in a post-trial evaluation questionnaire that I posted to all participants.

e) In order to assess compliance with and suitability of the accelerometers, I assessed valid accelerometer data and accelerometer wear time validation. When investigating PA level among adults, 3-5 days of data are recommended in order to approximate habitual PA from accelerometer data (Trost et al., 2005). In a study of 122 adults aged 18-79 years, Matthews et al. (2002) found that 3-4 days of objective data is required to achieve 80% reliability in assessment of PA in this population. However, Matthews et al. also observed that the PA behaviour of adults varies depending on the day of the week, with higher levels of PA being recorded at the weekend. Variance however was small, at 1%-8%, and occurred mainly in those of working age. Variance was less apparent in older adults. Matthews et conclude that 3-4 days of data is sufficient. Esliger et al. (2005) also recommend a minimum of five full days of data, including at least one weekend day. Based on these recommendations, I employed a 7-day monitoring procedure, with a 5-day, wear-time valid data requirement during analysis. This permitted me to reliably estimate the study outcome variables. The 5-day data requirement included one weekend day of wear time valid data. I felt this would be suitable for a sample in which the participants could either be in paid employment or retired. This also permitted a greater number of participants to be included in the analysis, should they be unable to wear the accelerometer for a day or two, or should the monitor malfunction for anything up to 2 days.

f) In order to address objective 1f, I recorded loss to follow-up in the main data analysis of the trial.

As recommended by CONSORT, I collected data on the baseline characteristics of participants, to provide information on all participants pertinent to feasibility, as well to determine the success of the randomisation procedure (see above). Also, where there was high attrition for an outcome measure, I assessed baseline data from those participants whose data was analysed separately to those participants lost to follow-up, as recommended by Dumville et al. (2006).

This is because baseline information from the whole sample may not accurately reflect that of those participants who completed the outcome and whose data was analysed; the information may also not accurately represent group comparability (Dumville et al., 2006). This is an especially important consideration when assessing feasibility, as it specifically details information on the subsample not included in analysis and can help with identifying potential attrition bias (Dumville et al., 2006).

Completion and attrition rate was calculated at baseline, T1 and T2. Completion rate was defined in 2 ways: as the number of participants who returned accelerometer devices with valid data and as the number of participants who had valid datasets for each self-report outcome measure and were thus included in analysis. In addition, the number of completed and returned self-report questionnaire booklets was recorded.

g) In order to assess completion rates of study questionnaire and therefore answer research objective 1g, loss to follow-up in outcome data analysis was recorded. Participants had to have completed outcomes and valid data at all 3 time points to be included in analysis.

h) In order to assess whether or not data collection and monitoring procedures were feasible, the number of questionnaires and monitors successfully distributed and returned on time and as instructed was recorded. Participants were asked questions pertaining to this in the post-study evaluation questionnaire. I also kept field notes of any difficulties encountered during the study.

Objective 2

a) and b) In order to address Objectives 2a and 2b, I carried out an 'Observational' analysis of the audio recordings of the PA consultations. This involved listening to the consultation recordings and completing a pro-forma (observational checklist) to assess the process and content of the consultation. This tool was designed for use in person by a third party during PA consultations. As this was not possible during this trial, I carried out a post-hoc assessment of

the tapes, using the observational checklist as a guide. I added checklist items pertinent to the structure of the joint consultations.

Post-trial evaluation questionnaires were also used in addressing objectives 2a and 2b, which included a section on the intervention (see Appendices). Further, intervention adherence was measured to contribute to the assessment of intervention feasibility. This was done by summing the total number of PA consultations successfully carried out with CRC-Ss and their partners allocated to the intervention group.

c) In order to address Objective 2c, I carried out a Situational Analysis (SA) of the PA consultations and produced an Ordered Situational Map of joint PA consultations with CRC-Ss and their partners. The map was intended to extract aspects of the consultation relevant to the assessment of feasibility, as well as important theoretical and other influences and components that could provide a platform from which to develop future research on dyadic PA consultations (ie. the outcome being to provoke a more in-depth analysis of the intervention). The map is not a final analytical product – it is intended to 'open up' the data and interrogate it (Clarke, 2005) and to provide a framework for future research and analysis. See Chapter 7.3.1 for full description and justification of SA.

Objective 3:

At baseline, 3 months and 6 months, outcome data was collected in participants' own homes. At each time point, I visited the couples in their home and asked them to complete a questionnaire booklet, stand on a bio-impedance scale and to wear an accelerometer for the next 7 days. I was present at baseline when the participants first completed the questionnaire booklet, in case they required any help or clarification and to make sure it was completed correctly. At the subsequent time points (3 and 6 months), participants were posted the questionnaire to complete themselves before my home visit, whereupon I collected it.

All of the following outcome measures were recorded at baseline (T0), three months (T1) and six months (T2).

a) In order to answer objective 3a, I collected the following outcome data from participants:

Objective measurement of PA – Accelerometers:

I used Actigraph GT3X+ accelerometers to record objective measurement of PA at T0, T1 and T2.

Initialisation of accelerometers:

The GT3X+ device stores accelerometer data in raw form in units of gravity called hertz (Hz). This rate of data collection can be selected by the user, from between 30Hz and 100Hz, in increments of 10Hz. The higher the value of Hz, the more frequently the device records activity i.e. the more data is recorded and stored on the accelerometer during a defined time period. As the rate of data collection increases, the battery life and days of memory limit of the device decreases. I programmed the accelerometers to record data at a sample frequency of 70 hertz. This comfortably permitted a full 7 days of battery life and device memory whilst optimising activity data recording. The accelerometer was set to record activity in 30 second epochs (ie. every 30 seconds). Participants were asked to wear an Actigraph GT3X+ triaxial accelerometer (Actigraph LLC, Pensacola, Florida) for seven consecutive days at baseline, three and six months during the trial to assess any change in PA. The accelerometer was removed when sleeping although could be worn when bathing and swimming for up to 30 minutes. Monitors were attached to adjustable elastic belts and worn over the right hip under clothing during waking hours.

I selected the following accelerometer outcome variables. These were determined by the research objectives:

1. Time spent in different PA intensities
2. Total activity counts per day

1. I assessed change in time spent in different PA intensities by applying the Freedson Adult 1998 defined cut points for sedentary, light, moderate and vigorous activities (Freedson et al, 1998). Cut points are applied to raw accelerometry data during the data processing stage and delineate the activity

count thresholds for different intensities of activity. There are various derived cut points that can be applied to accelerometry data, depending on the population being studied (ie. children, adults etc.) and the type of monitor used. Choice of cut points will influence outcome results on achievement of PA recommendations. Cut points should therefore be determined, as far as possible, based on the population under study and how the sample compares to the population from which the cut points were derived (Ridgers et al., 2011).

The Freedson cutpoints have been shown to have good agreement with time spent in different PA intensities amongst adults (Ainsworth et al., 2000). However, there is debate surrounding the use of cut points, as there is large variation in their definition of PA intensities, which impacts on the achievement of PA recommendations (Mota et al., 2007). This can lead to misclassification of people as active or inactive (Mota et al., 2007 cited in Ridgers et al., 2011). There are no cut-points for CRC-Ss, therefore I used Freedson as I thought the adult cut points would be most applicable to CRC-Ss and their partners.

2. The raw data collected by accelerometers is expressed as counts (Welk, 2002). I used the accelerometer data to detect change in average total activity counts per day, at each time point. This data provides a 'raw' indication of any change in activity, which may not be detected when cut points are applied to the data. This was important given the limitations associated with applying cut points to accelerometer data (as discussed above). Rosenberger (2013) recommends the use of total activity counts as a main outcome variable in studies monitoring PA with the use of accelerometers.

Information on downloading and processing data from the accelerometer and how this data was analysed can be found in section 7.3.1.

Self-reported PA – IPAQ questionnaire:

As recommended by Napolitano et al. (2007) and Schutz et al. (2011), PA was also assessed subjectively, using a self-report measure. I selected the long (self-report) version of the International Physical Activity Questionnaire (IPAQ), which was initially developed for cross-national monitoring of PA and inactivity. IPAQ measures time spent in low, moderate and vigorous activity across four domains

(work, transport, housework/gardening and leisure time) and time spent sitting in the previous 7 days. Assessment of IPAQ reliability has demonstrated the questionnaire to produce repeatable data (Spearman's Rho 0.8) and criterion validity has shown a median rho of 0.30, making it comparable to the majority of other self-report validation studies (Craig et al.,2003). Participants completed the IPAQ at baseline, 3 and 6 months during the trial. I will report the outcome categorically; that is, those with overall time spent in low, moderate and vigorous PA in the previous week, in keeping with the outcomes of the accelerometer data.

Self-reported SOC for PA

Stage of PA behaviour change was assessed using a validated SOC measure for the TTM for exercise behaviour (Loughlan et al., 1995; Dannecker et al., 2003). This instrument categorises participants into one of five categories: pre-contemplation (inactive, not thinking about changing PA), contemplation (inactive, thinking about changing PA), preparation (active occasionally, not regularly), active (regularly active for less than 6 months) and maintenance (regularly active for more than 6 months). Regular PA was defined as taking part in at least 30 mins of moderate intensity PA at least 5 times per week, in accordance with the recommended levels of PA. Validation results confirm strong validity of the SOC scale for exercise. Construct validity has demonstrated significant between-stage differences in adults, associated with behavioural, biometric and psychological variables collectively ($p<0.0001$) and independently ($p<.01$) (Cardinal, 1997). ANOVA tests have revealed significant differences between SOC categories in self-report levels of exercise behaviour in young adults ($F>7.34$, $P<0.01$) (Wyse et al., 1995); the scale has also demonstrated correct SOC assignation of 67.8 – 70.7% of subjects (Wyse et al., 1995).

b) In order to answer research objective 3b, I collected the following outcome data:

Mental well-being

Mental well-being was measured using the Hospital Anxiety and Depression (HADS) Scale. HADS is a brief, self-report questionnaire of 14 items, scored on a scale of 0-3 (3=higher symptom of frequencies), used to measure anxiety and depression over the past week (Herrman, 1997). HADS has been shown to be a valid and reliable self-rating scale of anxiety and depression in hospital and

community settings (Bjelland, 2002; Snaith, 2003) and with clinical and non-clinical groups (Herrman, 1997). HADS reveals high sensitivity and specificity in assessing symptom severity for both the anxiety and depression components of the scale. Brennan et al. (2010) report the accuracy of HADS as a case-finding instrument for anxiety and depressive disorders to be 0.56 – 0.82 (sensitivity) and 0.74 – 0.92 (specificity). HADS has demonstrated internal consistency (Cronbach's alpha 0.08) and concurrent validity reveals correlations between HADS and other commonly used questionnaires ranging from 0.49-0.83 (Bjelland, 2002).

Fear of Cancer Recurrence (FCR)

FCR in CRC-Ss was measured using the Fear of Cancer Recurrence Inventory (FCRI) (Simard and Savard, 2009). The FCRI is a multidimensional, self-report scale that uses a five-point Likert scale to measure cancer survivors' concerns about cancer recurrence. The measure has 42 items covering seven subscales, including triggers, psychological distress and coping strategies. The component subscales of the FCRI have together been shown to explain 64% of the variance in FCR (Simard et al., 2009). Evidence also supports internal consistency (alpha = 0.95) and construct validity with other self-report scales assessing FCR (r = 0.68-0.77) (Simard et al., 2009). The FCRI has been used in a number of studies to demonstrate the prevalence and evolution of FCR (Savard et al., 2013) and to investigate FCR in cancer populations (van de Wal, 2016; Simard et al., 2013).

c) In order to answer research objective 3c, health-related QOL in CRC-Ss was measured using the Functional Assessment of Cancer Therapy – General (FACTG) and The Functional Assessment of Cancer Therapy – Colorectal (FACT-C) questionnaires (Cella et al., 1993). FACT-G is a 27-item scale that assesses physical, emotional, social/family and functional wellbeing over the past 7 days. FACT-C is a 9-item scale that addresses concerns pertinent to CRC patients. FACT-G and FACT-C are reliable, validated QOL instruments for cancer patients that have been validated for use with patients, survivors and with older people (Cella, 1993; Overcash et al., 2001). FACT-G and FACT-C have demonstrated good internal consistency reliability and concurrent validity (Ward et al., 1999); scales and subscales have shown internal consistency reliability across diverse samples (alpha coefficient 0.84-0.89 and 0.85-0.91 respectively) (Ward et al.,

1999). A recent literature review of studies using FACT-C demonstrated reasonable internal consistency (Cronbach's alpha coefficient >60) (Ganesh et al., 2016). Good correlations have also been found between total and sub-scores of FACT-G and other health surveys (Pearson's correlation 0.7). Further, FACT-G and FACT-C have previously been used in studies with CRC patients and survivors (Cheville et al., 2013; Ramsey et al., 2000; Courneya et al., 2003; Yoo et al., 2013).

QOL in partners was measured using the short WHOQOL-Bref Instrument. The short form WHOQOLBref contains 26 items that have been extracted from the WHOQOL100. It measures the following broad domains: physical health, psychological health, social relationships and environment. It also includes one component on overall QOL and general health. The WHOQOL-BREF has been shown to provide a reliable and valid alternative to assessment using the WHOQOL-100 and to be useful in the evaluation of treatment efficacy (WHOQOL Group, 1998). A cross-sectional sample of almost 12,000 adults in 23 countries, demonstrated excellent internal consistency, reliable construct validity and content validity for each domain and overall (Skevington, 1999). Cronbach's alpha showed acceptable internal consistency ranging from 0.80 – 0.82 (>0.7); t-test demonstrated significant discriminant validity for each domain ($p<0.01$) and analysis of correlations demonstrated strong construct validity (>0.50) (Skevington, 1999).

d) In order to answer research objective 3d, participant self-efficacy was measured using the General Self-Efficacy Scale (Schwarzer and Jerusalem, 1992); a 10-item psychometric self-report instrument, designed to assess optimistic self-beliefs to cope with a variety of different life demands (http://userpage.fu-berlin.de/health/selfscal.htm). The GSE Scale is the most commonly used screening tool for self-efficacy (Grammatopoulou et al., 2014) and is validated for use with numerous populations of adolescents and adults over 12 years of age (Schwarzer and Born, 1997, Schwarzer et al., 1999; Luszczynska et al., 2005). The GSE demonstrates significant concurrent and prognostic validity (correlation range = -0.57- 0.59) (Schwarzer 1992; 2014).

POC was measured using a 40-item, five-point Likert scale (Marcus et al., 1992) to assess the degree to which an individual uses experiential and

behavioural processes of behaviour change. Factorial validity of the ten POC factors has revealed a significant interaction between SOC and POC variables (Wilks' λ=0.746, $F(10,386)=6.07$, $p<0.001$) (Bernard et al., 2013). These results have been consistent in construct validation studies of the POC, which have shown the measure to provide valid assessments in TTM-based observational and intervention studies, with a range of population groups and invariantly across age, sex and ethnic group (Paxton et al., 2008; Dishman et al., 2010 Bernard et al., 2013). DB was measured using a 6-item, five-point Likert DB questionnaire (Marcus et al., 1992; Marcus et al., 1992), to assess participant perceptions of the pros and cons of participating in regular PA. Total scores for the three pros and three cons items are generated for comparison. There is no validity data for this specific measure, although content, factorial, concurrent, and construct validity, as well as internal consistency and test-retest reliability, has been established for DB scales (Plontikoff, 2001).

e) In order to answer research objective 1e, I measured the 'quality' of the relationship between CRC-Ss and their partners using the validated relationship quality measures from the English Longitudinal Study of Ageing (Marmot et al., 2003), which assess 'social support' and the quality of the respondent's social relationship their partner. Specifically, respondents are asked about the presence of positive support from their partner (how much they understand the way the respondent feels about things, how much they can be relied on if the respondent has a serious problem and how much the respondent can open up to them to talk about worries) and about negative relations with each other (how much others criticise the respondent, how much they let the respondent down and how much they get on the respondent's nerves). Positive and negative support items are scored as 1='not at all' and 4='a lot', such that higher numbers indicate more of each type of support. Three questions on the receipt of social support for PA in the previous week were also included, to assess whether the intervention changes perceived social support for PA.

7.2.8: *Sample size calculation*

The focus of pilot studies should be feasibility, not statistical significance…sample size justification should be based on considerations, calculations and analyses that directly align with primary goals of the pilot study

- Moore et al., 2011

I did not carry out a formal sample size calculation for the study. There was no relevant data from a PA intervention trial using accelerometer data as the primary outcome measure, with a colorectal cancer population, upon which to base a power calculation. Further, the primary objectives of the study were feasibility objectives. If outcome data were to report change in parameters within and/or between intervention groups, the results would indicate a positive impact of the intervention and suggest that a more comprehensive, statistically powered RCT be undertaken.

The study sample size was based on the primary feasibility objectives and on the practicalities of data collection. I aimed to recruit 30 couples to the study, where one partner had been diagnosed with CRC in the previous 32 months. This would result in 15 couples being randomised to each arm of the intervention. A sample size of 12 per group is recommended as a 'rule of thumb' for pilot studies and feasibility calculations (Julious, 2005 and Belle, 2002). I therefore intended to recruit 30 couples with the aim of retaining at least 24 couples for demonstration of study feasibility and inclusion in final data analysis.

In 2008, there were 1616 newly diagnosed cases of colorectal cancer in the West of Scotland (West of Scotland Cancer Network). Of these diagnoses, 1056 were Dukes stage A-C2 and 55 were Dukes stage D. A total of 505 stages at diagnoses were recorded as inapplicable or unknown. In the same year, there were approximately 120 newly diagnosed cases of CRC on consultant surgeons lists at Gartnavel General Hospital (information provided by Mr Richard Molloy, Consultant General Surgeon). Survival from colorectal cancer is greatly impacted by stage of cancer and tumour location at diagnosis; however, based on observed colorectal cancer survival rates, of these 120 newly diagnosed cases, approximately 75% (n = 90) will still be alive at one year and 70% (n=84) at 2 years following diagnosis (ISD Scotland and information provided by Mr Richard

Molloy, Consultant General Surgeon). Based on a previous randomised trial of exercise and QOL in CRC-S (Courneya et al., 2003) and a previous study that recruited partners of prostate cancer survivors to a couples-based strength training trial (Winters-Stone et al. 2012), I estimated that 22% (n=38) CRC-S and their partners, could potentially be recruited to the study.

The sample was also a non-probability convenience sample; subjects were selected due to their accessibility and the practicalities of data collection. Each couple enrolled to the trial would receive 6 home visits throughout the duration of their participation in the study. Recruiting 30 couples – provided they are retained in the trial – was equivalent to a total of 190 home visits in the Greater Glasgow and Clyde area, over 12 months, by one researcher. It was not practicable to recruit beyond 30 couples and was therefore not ethical to enrol beyond this number. Moore et al. (2011) recommend at least 12 participants for pilot studies in part because the number is practical for early-stage researchers to recruit from a single centre whilst still allowing the collection of valuable preliminary data.
The sample was considered large enough to provide useful information about the feasibility aspects being assessed in the study (Thabane et al, 2010). By design, the study was not powered to determine the effectiveness of PA consultations on the PA levels of CRC-Ss and their partners. This important research question should be addressed by a larger multi-centre trial.

7.3.0: *Randomisation and allocation concealment*

All couples who took part in the study were randomly assigned to either Group One (Intervention) or Group Two (Usual Care) using blocked SNOSE randomisation (discussed below). All couples had an exactly equal chance of being assigned to each group.

To prevent any researcher influence over which couples were randomised to intervention or control arms, I used a blocked SNOSE randomisation procedure (Doig and Simpson, 2005). This procedure allowed me to conceal the randomisation sequence from myself, by myself, using sequentially numbered, opaque, sealed envelopes (SNOSE). Figure 9 is taken from Doig et al. (2005) and illustrates how SNOSE randomisation is carried out. Firstly, I produced envelopes for the intervention arm and control arm by completing the steps in Figure 9 for

each group. I assembled 20 sealed intervention arm envelopes and 20 sealed control arm envelopes (40 envelopes in total).

Then, because the number of couples who would be recruited to the study was uncertain, I used a block randomisation process with the envelopes, to ensure balance in the trial after the enrolment of each block of couples. This involved shuffling blocks of four envelopes (two intervention, two control) and blocks of two envelopes (one intervention, one control). In combining the blocks of envelopes, I flipped a coin rather than simply alternating between blocks of two and blocks of four – this ensured that the allocation sequence could not be anticipated (Doig et al., 2005). The envelopes were then placed in a box, ready for use. Each time a couple consented to participate, I opened the next envelope in the box following collection of baseline data, to inform me which group the couple were allocated to. This process minimised researcher bias. It allowed me to carry out a completely objective randomisation procedure when I was the only researcher on the project.

7.2.9: Blinding

Given the nature of the intervention, it was not possible to blind participants. I also could not be blinded at every stage of the trial. This presents problems of researcher bias. However, in an attempt to reduce bias, I collected baseline data prior to randomisation.

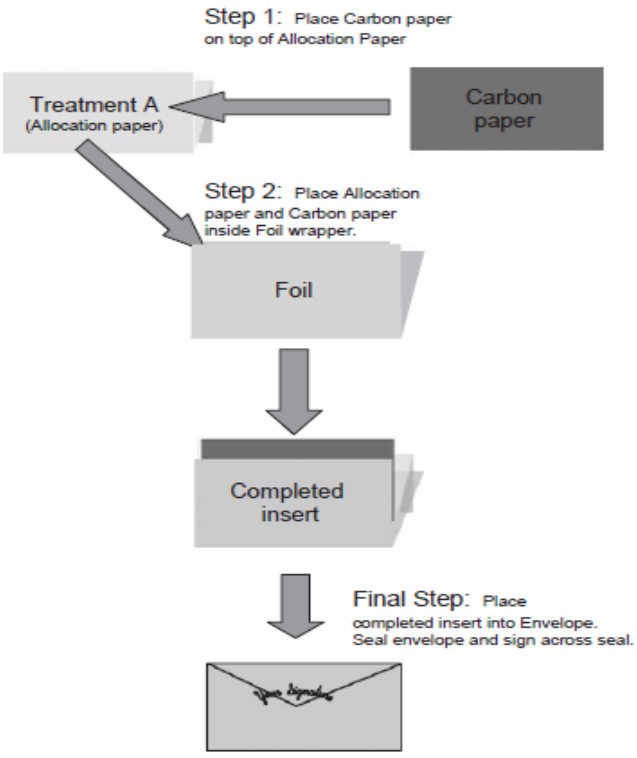


Fig. 1 Preparation of envelope insert.

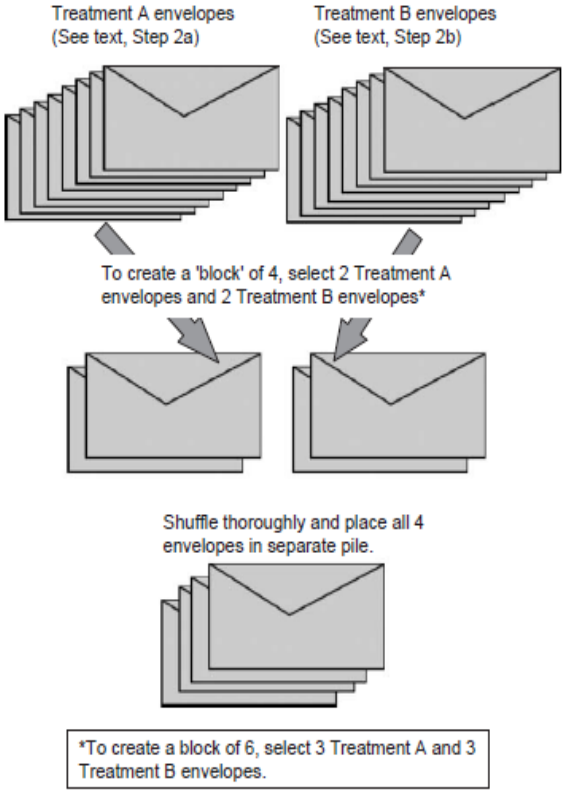


Fig. 2 Permuted block randomization (blocks of 4 and 6).

Figure 9 – *Blocked SNOSE randomisation procedure*

7.3.1: *Data analysis*

Accelerometer data:

The 'raw' accelerometry output (accelerometer count per minute, (cpm), averaged over the monitoring period was used as a measure of total physical activity and was also used to quantify the amount of monitored time spent in sedentary behaviour and moderate and vigorous PA using validated cut-points (Freedson et al., 1998). All outcomes were explored, including time spent in sedentary, light, moderate and high intensity activity; however, the main outcome of interest was total activity counts. Sustained zero counts were used to determine non-compliance.

The accelerometer data was screened for spurious results. This was to ensure that the outcome variables were not contaminated by extreme high or low values which would impact on the validity of the accelerometer data.

Missing accelerometer data: Complete days of accelerometer data that were missing were not included in accelerometer data analysis. Some accelerometry studies utilise data modelling techniques, which base data for missing days on average count data from other days that meet the minimum wear time requirements (for example, a missing weekday would be based on another missing weekday; one missing weekend day would be based on the other). However, carrying out such procedures is highly debated. Basing missing days on existing data could potentially over inflate the activity counts for an individual (Esliger et al., 2005). Modelling assumes that an individual's weekday activity is similar on all weekdays, and that activity on each weekend day is also similar. Whereas this may be the case for young school-aged children, it is not appropriate to make the same assumption of other, adult populations (Esliger et al., 2005). Averaging the activity count values for existing days of data for application to missing days could demonstrate an inflated level of PA for an individual. Therefore, only data that met wear time criteria and the minimum number of days was included in analysis. There is no definitive recommendation as to whether or not to model or exclude missing data from analysis.

Periods of missing accelerometer data will always affect outcome variable results, even if data is obtained for the total duration of monitor programming (in this instance, seven days). For example, if a participant removes the device for a period of time, it would remain motionless and resultant zero counts would have the effect of reducing an individual's activity count. If, on the other hand, the monitor was carried in a handbag for any length of time, this could potentially increase an individual's activity count for a given outcome variable. Periods of missing accelerometer data will always have an impact on results and should be noted as a limitation accelerometer studies.

Trial questionnaire booklets

All questionnaire data for intervention outcome instruments was inputted manually into SPSS. 50% of the data was then independently checked and cleaned for errors and to maximise accuracy by a visiting student to The University of Stirling.

IPAQ analysis: Total scores for IPAQ were computed by summing the duration (in minutes) and frequency (in days) for all types of activities in all domains (leisure time PA; domestic and gardening activities; work-related activity and transport-related PA). Activity-specific scores were then calculated so as to categorise results into one of three categories of PA: low, moderate or vigorous.

HADS analysis: HADS is made up of two subscales – anxiety and depression – the scores for which range from 0-21. Scores for each subscale were calculated and a score for the entire scale (range 0-42) was given. Higher scores indicate higher distress.

GSE analysis: GSE responses were scored on a four-point Likert scale. The sum of responses to all 10 items was calculated and a final composite ranging from 10-40; the higher the total score, the higher the GSE.

FCR: A total score for FCR was calculated by summing the scores of the 42 items on the scale. Higher total score indicates higher FCR.

Relationship support: Relationship items on the questionnaire were assessed individually. The higher the score, the higher the perceived relationship support and support for PA.

The feasibility and intervention outcomes were analysed descriptively and narratively. For the clinical endpoints, only descriptive statistics, mean (standard deviation) for continuous outcomes and raw count (%) for categorical outcomes, were reported (Eldridge et al., 2016; Forero et al., 2015).

Descriptive statistics, including frequencies, means and standard deviations were used to summarize all intervention outcome measures at baseline, three and six month time points. Demographics, educational attainment, household income, employment status and general health questions were summarized with frequencies and percentages.

Trends in scores over time of the responses of couples enrolled in the study were examined for family patterns. The scores of all participants were used independently in the data analysis.

I felt that anything other than a descriptive analysis of change over time in the data would be inappropriate given the small sample size (and even smaller numbers of valid datasets following attrition over the course of the trial). Carrying out significance testing on the data would be beyond the capabilities of the data itself and therefore not yield any valid or informative results. Statistical testing for efficacy of the intervention lies out with the remit of this feasibility pilot study (see Chapter Six).

My plan for data analysis was guided by a statistician Kate Howie and a human geographer Richard Kyle at the University of Stirling, as well as recommendations for the reporting of data from feasibility studies (see Chapter Six).

Situational Analysis of Audio recordings of PA consultations

*The conditions **of** the situation are **in** the situation*

-Clarke, 2005

Situational Analysis (SA), pioneered by Adele Clarke in 2003, is a regenerated approach to grounded theory within qualitative analysis, which analytically addresses the complexities of social life using situational maps and analysis approaches as supplements to basic social process analyses characteristic of grounded theory (Clarke, 2003). Clarke defines three types of map: (1) *situational maps* that lay out the important human, non-human, discursive and other elements

in a given research situation of inquiry and provoke analysis of relations among them; (2) *maps of social worlds and arenas*, which lay out collective actors, key non-human elements and the arenas of discourse within which they engage and (3) *positional maps*, which lay out the positions taken, and not taken, with regards to discord in a given situation of inquiry (Clarke, 2005). These maps construct social research in detailed and complex ways that permit an appreciation of "complications, messiness, and denseness of actual situations and differences" (Clarke, 2005: 28). SA brings to the fore factors that are ordinarily considered contextual or environmental and considers them as constitutive of the situation; the maps are used to increase the visibility of complexity (Wulff, 2008).

Although a relatively recent analytic method, SA is gaining traction in the field of qualitative social and health research. For example, SA has been recommended for use to effectively inform the practice of family therapy (Wulff, 2008) and for practice-orientated social science working with qualitative research methods (Mather, 2008). Further, SA has been successfully applied as a methodology for exploring midwifery students' experiences of achieving competency (Licquirish et al., 2011); as a method for studying and supporting the renewal of complex public health systems (Martin et al., 2016) and to inform research on long-term unemployment (Aldrich et al., 2015). By applying situational mapping, Aldrich et al., for example, elucidated the contradiction of those who are long-term unemployed being simultaneously 'activated' and 'stuck' with regards to job seeking, and how this contradiction was shaped within North American contexts (Aldrich et al., 2015). SA has also been applied to a study on the perceptions of changing family boundaries in the process of leaving an abusive partner (Khaw, 2012). Situational maps were used to develop family-level theory of the process of leaving and were deemed a useful, practical and adaptable mode for qualitative research (Khaw, 2012).

SA is an adaptable qualitative analytic method that evidence demonstrates to be applicable in micro and macro level situations and when the dynamics and elements of a situation are unknown or complex; this makes SA a potential valuable tool for feasibility research and intervention development. To the best of my knowledge, this is the first primary research study to apply SA to feasibility and the development of a health behaviour intervention.

I applied SA and the use of *situational maps* to PA consultations in this study. Situational maps can be applied to a wide range of research circumstances; including interviews, ethnographic research and visual and oral research and allow researchers to:

> *…draw together studies of discourse and agency, action and structure, image, text and context, history and the present moment – to analyse complex situations of inquiry*
>
> -Clarke, 2005

In other words, situational maps allow the researcher to analyse a variety of influences and underlying empirical and theoretical effects on a given research setting; to assess the conditional elements that are constitutive of a given situation, rather than merely assessing those elements that surround, frame or contribute to it (Clarke, 2005). In this study, situational mapping assisted in locating PA consultations within a wider theoretical, social, physical and environmental framework.

Situational mapping involves carrying out analysis on un-coded, carefully read and extensively 'digested' qualitative data (Clarke, 2005). Firstly, the most analytically pertinent human, nonhuman, material and symbolic/discursive elements in the situation (as framed by those in the situation and by the analyst) are descriptively laid out in a 'messy' situational map, or maps (Clarke, 2005). These first maps are intentionally very messy, as they are easy for the researcher to work with and edit (see Appendices for messy maps). Next, using the messy map(s) as data, an 'ordered' situational map is produced, laying out the important elements of the situation under different categories. Clarke suggests thirteen categories under which to order data (see Chapter Eight, Figure 12). It is not essential to have all of these however, and the analyst can modify or create other categories using their own messy map; what appears in a situational map is based on the situation under inquiry. The situational map is striving to include as much pertinent information as possible; it is unlikely include absolutely everything. The situational map can be revised, augmented and edited as analysis progresses.

Once a situational map is complete, the next step is to carry out a 'relational analysis', based on the situational map. This involves applying your research questions to the data and looking for connections and links between different elements on the map. You take each element in turn and think about it in relation to each other element on the map; this process assists the researcher in deciding which relations are important and which to pursue (Clarke, 2005).

I carried out situational mapping on the transcripts of 12 audio-recordings of PA consultations, as well as field notes. I descriptively laid out analytically pertinent elements from each consultation in a number of messy maps (see Appendices). I then used these messy maps as data to produce an Ordered Situational Map of PA consultation (see Chapter Eight, Figure 12). In this map, I ordered each of the elements under the categories recommended by Clarke (2005), as well as a distinct category that emerged from the data (see Chapter Eight, Figure 13). Broadly, and in line with SA, I then interrogated the data using the following questions:

1) Who and what are the main influences during the consultation?
2) Who and what matters in the consultation?
3) What elements 'make a difference' during the consultation?

The aim was to produce an Ordered Situational Map and preliminary relational analysis to provide a platform for future research and from which to develop the intervention.

By carrying out SA I took a reflexive perspective on the people and other contextual factors, such as space and environment, that shape the course and, by implication, the outcome of the consultations. Applying SA to the consultation tapes allowed me to assess the influence of the participants, the researcher and the environment on the consultations and to establish possible theoretical and mechanical underpinnings of the interaction that might assist in the assessment of feasibility and development of future research.

I carried out the SA in order to arrive at an empirically grounded and contextually sensitive understanding of the intervention and interactions during the consultation (ie. between the couples and the couples and the researcher). For feasibility purposes, I was particularly interested in the impact of the partner during

the consultation. I used SA techniques to investigate why and how the consultations might work when involving a partner and what, therefore, could be anticipated or developed in a future study of this intervention.

The success of this intervention is rooted in interpersonal rapport, between the couple and the couple and the researcher. This rapport could potentially make the difference between 100% attrition and no attrition in a trial. The interaction could determine the success or failure of the consultation; the quality and nature of the dyadic and triadic interaction could, for example, have a big impact on PA outcome, or little effect on PA outcome but a huge effect on whether or not couples persevere with the trial. Further, as is the rationale behind this study, the interaction between the couple could potentially impact on the PA outcomes of both partners, therefore trying to establish the possible mechanisms through which the interaction might encourage or inhibit positive PA behaviour change is an essential part of determining the feasibility of this intervention and a larger trial. SA and mapping of the consultations helped to contextualise and make sense of the quantitative outcomes gathered during the study.

The qualitative analysis of the tapes was primarily concerned with providing depth of analysis to the feasibility objectives of the study and guiding future research, by beginning to develop a deeper understanding of the constitutive elements of the consultations. Analysis might identify behavioural determinants that are facilitating or preventing progress during the intervention and possible areas that need addressed to optimise the potential of achieving the desired outcome.

Post-trial evaluation questionnaires

I constructed the evaluation questionnaire myself, based on the feasibility objectives of the study. The questionnaire therefore, was not a validated research instrument. Hence, I did not aggregate individual items into overall domain or total scores. I examined the responses in the questionnaire on a question-by-question basis. Further, I felt that examining each question in isolation would be more insightful to my feasibility objectives and provide useful information on how the study design and intervention can be refined for a larger study.

7.3.2: *Additional Information*

Ethical considerations

Confidentiality: All participant personal information and data generated throughout the study was stored in password protected databases, in line with the Data Protection Act 1998 and the University of Stirling's Data Protection Policy. Each participant was given a study identifier number so that study data could be matched confidentially to individual participants. Hard copies of questionnaires and consent documents were stored separately in a locked filing cabinet at the University of Stirling.

Informed consent: Informed consent was obtained at two stages of the recruitment process. First, eligible CRC-Ss gave verbal consent to recruitment nurses for their contact details to be forwarded on to the researcher. Secondly, I obtained written consent from both CRC-Ss and partners before undertaking baseline assessment. All participants signed a consent form (Appendices), which was securely stored in a locked filing cabinet at the University of Stirling. Participants were informed that they were under no obligation to take part in the study and that they could withdraw at any time and without giving a reason. Participants were also informed that their usual care would in no way be affected whether or not they chose to take part in the study.

I ensured to the best of my ability that participants were fully informed about all aspects of the study before they consented to take part. Informed consent is especially problematic in feasibility studies, where participants are often unaware that the research they are taking part in is not a definitive study but rather a preliminary study to inform future research (Kirkby, 2012). In order to overcome this potential ethical problem, I incorporated the feasibility nature of the study into each step in the recruitment and consent process. I ensured that the nurses were fully informed about the study and were able to supply accurate information to potential participants when telephoning to seek consent to be contacted; I ensured that the study title explicitly referred to the study as being feasibility and I further discussed the feasibility nature of the study with participants when obtaining written consent at initial home visits.

Participants could withdraw from the study at any time and without giving a reason. I could also withdraw participants from the study intervention if I

considered it to be in their best interests. There were two options for participant withdrawal:

1. Complete withdrawal from both the study intervention and provision of data
2. Partial withdrawal where the participants were withdrawn from participation in the intervention but continued to provide data

Consent was sought to retain data already collected from any participants who fully withdrew from study. In order to inform acceptability outcomes and improve the development of a larger trial, fully withdrawn participants would be asked if they would be willing to provide reasons for withdrawal.

Burden: Imposing excessive or unnecessary burden on participants was another key consideration when designing the study. Given the face-to-face contact required by the intervention and the relative frequency of researcher visits to participants' homes, burden was a concern when developing study protocol. In particular, potential burden was an issue when selecting outcome measures. Further to frequency of researcher contact, participants were being asked to wear accelerometers for a total of three weeks over the six months they would be in the study, as well as completing an extensive questionnaire and consenting to the collection of bio-impedance data. Therefore, a further outcome measure – the Chester Step Test – was rescinded from the study.

Ethical approval:

The study received research ethics approval from NHS Greater Glasgow and Clyde.

Service user involvement

Service user involvement was an important element in the development and execution of the study protocol. NHS Scotland's Patient Focus Public Involvement (PFPI) strategy advocates that whenever possible, service user involvement should be built in to the planning, development and delivery of work and research programmes (NHS Quality Improvement Scotland, 2009). The PFPI strategy is committed to providing meaningful opportunities for patient and public involvement, at as early a stage as possible, which provide plenty of background

information and are open, honest and clear to all involved about what being asked to do and why it might make a difference. Therefore, during the developmental stage of the study, I recruited two CRC-Ss and their partners involved with the charity Bowel Cancer UK, to provide advice and feedback on the intervention, outcome measures and study implementation. The couples remained advisors to the study throughout its duration.

Chapter Eight: Findings

In the following chapter I will present the results of the pilot study RCT and embedded qualitative study. The structure of this chapter follows that of the study objectives (see Chapter Five).

8.1: *Objective One*:

To evaluate the feasibility of trial and data collection methods by answering the following questions:

a. What is the eligibility rate and what proportion of patients are ineligible and why?

Nurses screened the records of 199 colorectal cancer patients from the previous 30 months (January 2009 – June 2011). Of these patients, 76 (38.2%) were eligible for inclusion in the study. The flowchart in Figure 9 details the number of patients who were screened for eligibility for the trial (see Chapter Seven, Table 6 for eligibility criteria), the number of patients excluded following screening and the reasons for exclusion. Of the 199 patients screened, 90 did not meet the inclusion criteria and were therefore ineligible to take part in the study. The eligibility rate was therefore 55% (109/199).

Reasons for ineligibility at point of screening:

Table 7 below details the reasons why patients were excluded due to ineligibility at the point of screening. Of the 199 patients screened for eligibility, 75 (37.7%) were excluded because they did not have a partner. Of those patients, 56 (74.7%) were noted as living with or nearby to another close relative or friend (including offspring, siblings and other family members). Seven patients were receiving ongoing treatment at the point of screening and eight were diagnosed with metastatic disease, therefore these patients did not meet the eligibility criteria.

Table 7: *Reasons for ineligibility*

Reason	**Number of exclusions: n (% of total screened)**
No partner	75 (37.7)
Treatment On-going	7 (3.5)
Metastatic disease	8 (4.0)
Total	90 (45.2)

When asked their views on the eligibility criteria in interview, the recruitment nurses questioned the exclusivity of having a partner:

N1: why is it not worth just looking at people on their own? You know, what was the issue with having to have a partner?...

N1: …What about sons, daughters?

N2: Friends. A lot of women will go a walk with the dog at night, but with their pal.

N1: If it's a support thing, then support could be anyone

Table 8*: CRC-S participant disease information*

	Intervention Group (n = 15)	**Control Group** (n = 14)	**Total (n=29)**
Stoma: n (%)			
Yes	1 (6.6)	4 (28.6)	5 (17.2)
No	14 (93.3)	10 (71.4)	24 (82.2)
Missing	0 (0)	0 (0)	0 (0)
Cancer stage: n (%)			
Dukes A	3 (20.0)	5 (35.7)	8 (27.6)
Dukes B	8 (53.3)	7 (50.0)	15 (51.7)
Dukes C	4 (26.7)	2 (14.3)	6 (20.7)
Missing	0 (0)	0 (0)	0 (0)
Cancer location: n (%)			
Colon	11 (73.3)	8 (57.1)	19 (65.5)
Rectum	4 (26.7)	5 (35.7)	9 (31.0)
Caecum	0 (0)	1 (7.1)	1 (3.4)
Missing	0 (0)	0 (0)	0 (0)
Months since surgery/treatment: n(%)			
0-6 months	3 (20.0)	4 (28.6)	7 (24.1)
7-12 months	6 (40.0)	4 (28.6)	10 (34.5)
13-18 months	1 (6.7)	3 (21.4)	4 (13.8)
19-24 months	1 (6.7)	0 (0)	1 (3.4)
25-30 months	4 (26.7)	3 (21.4)	7 (24.1)
Missing	0 (0)	0 (0)	0 (0)

Table 8 details the disease information of the CRC-Cs study participants. The majority of CRC-Ss in the sample (58.6%) had completed their surgery and/or treatment within the previous year, suggesting that this could be a preferential time at which to recruit from this population. Further, in interview, the recruitment nurses suggested that the best time to approach a patient about participation might be as soon as possible after the conclusion of surgery and oncology treatment. The reason for this they said, is that at that point is the end of patients' hospital experience and they are only coming back at 3 or 6 monthly intervals to the clinic for their check-ups:

We've always known that patients who have chemo or treatment, or treatment after their surgery, then they go through that feeling of isolation when their treatment is finished. Or surgical patients go through it much sooner; they've been through, they've had their op, they've gone home, clinic at 6 weeks then 'oh my god, it's all over. There's isolation then. It's delayed with patients who are having chemo. And it's almost worse, cos they've had more contact with the hospital and all of a suddenly that's it, all their treatment is finished – what happens now?

- N2

The nurses pointed out however, that patients can't be approached too soon if they have had surgery, as the healing process takes time – often months – and a PA intervention at this juncture would not be appropriate:

If you look at someone's physical activity six weeks post-op, you're not getting a true reflection of what they're like.

- N1

This is not necessarily the case, they said, with patients who did not receive surgery and who have completed radio or chemotherapy treatment. These patients normally have a Dukes stage A or B diagnosis and could be recruited immediately following treatment. The most recent surgical participant recruited to the study was 8 weeks post-surgery/treatment. Seven participants (24.1%) were between 25 and 30 months post-surgery/treatment. A total of five (17.2%) CRC-Ss had stoma bags. In keeping with CRC statistics, almost all of the participants had been diagnosed with cancer of the colon or rectum (96.6%). (ISD Scotland). There was an even spread of participants across Dukes diagnosis stages A-C, with 15 (51.7%) participants diagnosed with Dukes stage B CRC-C.

b. What are the consent, recruitment and retention rates to the trial?

Table 9: Recruitment (eligibility)

Eligible patients: n (%)	**76 (100)**
Eligible patients contacted by nurses: n (%)	49 (64.5)
Eligible patients not contacted by nurses: n (%)	27 (35.5)
Eligible patients contacted by nurses: n (%)	**49 (100)**
Consented to be contacted by researcher: n (%)	43 (87.8)
Declined to be contacted by researcher: n (%)	6 (12.2)
Excluded following contact by researcher: n (%)	9 (18.4)
Recruited and randomised: n (%)	29 (59.1)

The consent rate was 59.1% (29/49). Nurses contacted a total of 49 eligible participants (64.5%), of which 43 couples (87.8%) consented to be contacted about the study. Of these, 29 couples (59.1 %) were ultimately recruited and randomised. Six patients who were contacted by the nurses declined to give consent to be contacted about the study by the researcher.

The nurses ceased recruitment once the target sample had been met therefore there were 27 eligible patients who were not contacted after the sample was reached. This raises the question of how the nurses selected which participants to contact on the list. During their post-trial interview, the recruitment nurses discussed how they contacted those patients who they thought to be more likely to consent to being enrolled in the study.

Reasons for exclusion following consent to be contacted

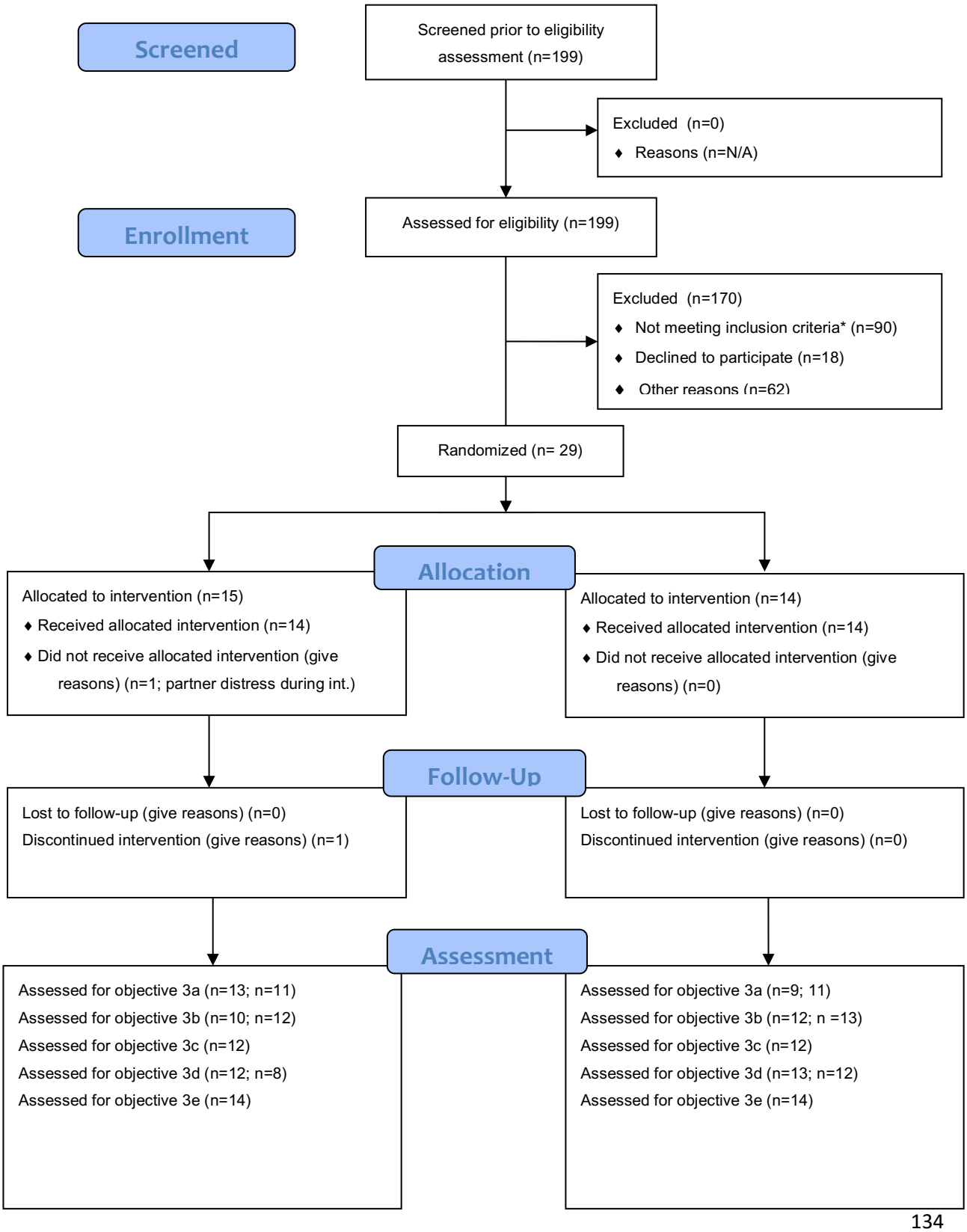
Of the six patients who declined to be contacted by the researcher about the study, three did so because their partner would not consent to take part; two patients felt that they were not well enough and one was simply 'not inclined' to take part in a research study.

Nine (18.4%) couples declined to take part after giving their consent to be contacted, at the point of arranging the first home visit. Reasons for this included poor health of one partner, concerns about extent of involvement in the study, being unwilling to answer personal questions, one half of the couple not wanting to take part and doubts about personal relevance of the study to one or both partners.

Three couples who consented to be contacted about the study declined to take part following the first home visit. In each case, the couples declined before baseline data was collected and therefore had not been randomised. One couple misunderstood the purpose of my visit and of the study; they thought I was there to receive feedback on their experience of the NHS. The CRC-S in one couple felt that the questionnaire was too long, did not want to wear the accelerometer and reported a pre-contemplative SOC (ie. was not thinking about increasing his PA). The third couple decided not to participate as they felt they were in the Maintenance SOC (ie regularly physically active for longer than 6 months) and the partner refused to wear an accelerometer.

29 (96.7%) of the target sample of 30 couples were successfully recruited to the study and randomised following the collection of baseline measures. 100% (29/29) of participants were retained in the trial for the full 6 months. Figure 10 presents a CONSORT flow diagram of recruitment to the study.

Figure 10: CONSORT Flow Diagram for Pilot and Feasibility Trials: CRC-Ss



c. Is the recruitment strategy feasible and acceptable to participants and recruitment nurses?

Table 10: *Recruitment (mean ±SD)* *

	Intervention (n=16)		Control (n=26)	
	CRC-S (n=8)	Partner (n=8)	CRC-S (n=13)	Partner (n=13)
I was happy with the way I was recruited to the study	4.8 (0.5)	4.6 (0.5)	4.4 (0.5)	4.6 (0.5)
I was fully informed about what taking part in the study would involve	4.8 (0.5)	4.6 (0.5)	4.5 (0.5)	4.9 (0.4)

*score range 1-5 (1-Strongly disagree; 2-Disagree;3-Neutral;4-Agree; 5-Strongly agree)

100% of couples who consented and were recruited to the study were randomised to either the intervention or control arm of the trial. Participants in both arms reported overwhelmingly that they were satisfied with how they were recruited to the study and how they were randomised to either intervention or control groups (see Table 10 above).

Four recruitment themes emerged from analysis of the interview with the recruitment nurses and study field notes: (1) time constraints; (2) eligibility constraints; (3) the nurse-patient relationship and (4) participant information:

(1)Time constraints:

The nurses spoke of doing the majority of recruitment at the end of the day, often out with their working hours. They said that this was for two reasons: to try to catch potential participants at home and to avoid having to rush recruitment conversations during the day, when they were working and usually had little available time. The nurses said that the recruitment calls took time, as they would first catch up with patients - who often wanted to discuss their current health and medical concerns – before addressing the purpose of the call. As one nurse said:

… if you started that kind of conversation when you were rushing to a clinic or going to see somebody on the ward, you would get caught up and you felt you were then rushing it so…it was probably easier for us to do it at the end of the day.

-N1

Despite this, the nurses did not report the recruitment process itself to be overly time-consuming:

… it was a bit of the day, every day. You know, so it wasn't like you were sitting for two or three hours trying to find people; it was just something we did as the day went on and then got some names and thought we'll try and phone three or four people at night. Hour-wise or percentage-wise time, it's very difficult to say.

- N1

(2) Eligibility constraints:

The nurses felt that the eligibility criterion of having a partner or a spouse was one of the main obstacles to recruitment. This was for two reasons. Firstly, the nurses found this criterion to be restrictive, given that many patients would have otherwise been eligible to take part:

N1: Initial recruitment of patients was a bit difficult – finding patients that were suitable… Just because of the criteria – that was the first thing

N2: Yeh, it was getting patients that had a partner or a spouse was probably one of the main issues and then once we'd checked that out, it was then checking where they were in their treatment and whether or not they were finished chemotherapy and that took the time; sometimes checking up the computer or going through old letters

N1: why is it not worth just looking at people on their own? You know, what was the issue with having to have a partner?

Secondly, the nurses found recruitment difficult because once an eligible patient with a partner was found, the partner had also to meet eligibility criteria and be willing to take part:

N1: …I think it was probably the spouse/partner thing that was making it difficult; a partner that was going to be suitable to take part in the study. I think that was probably the main difficulty.

N2: Aye, because you know their partners or their spouses a bit, but not as well as, obviously, you know the patients.

The nurses did not speak to the partners directly during recruitment; partners gave verbal consent to the patient, who consented to the nurses to be contacted by the researcher on their behalf.

(3) Relationship

The nurses described their relationship with the patients as integral to the recruitment process. They felt that patients' (and partners') decision to give their consent to be contacted by the researcher about the study was influenced by their knowledge of and relationship with patients and that without that connection, recruitment might prove more difficult:

N2: I think probably what went well was we know the patients. I think we were able to recruit for you because we know these patients really well. I think for somebody to do this study by just mailing patients, cold-calling – I don't think it would work the same. Without a doubt.

N1: And that was the big advantage wasn't it – we have that relationship with them. Yep, definitely.

N1: Yeh, I think that's right – it was the fact that we get to know these patients so well…

In the view of the nurses, the relationship they have with patients was connected to the reason why patients decided to take part in the study. Following on from the above quote, N1 immediately goes on to say *"*and they do want to give something back*"*. When asked about this directly, the nurses elaborate on this point:

R: Why do you think people were quite willing to take part?

N2: I think as you say [N1], it's to give something back, isn't it.

N1: I suspect that's the main thing. They just want to help other people, they want to, you know, they've had good care and they've done well and they just want to…

N2: I mean, it's a bit of a giving back to the team that have looked after them here but also feeling that maybe they can help other patients going to go through the same procedure in the future

This was echoed in the reflections of the participants themselves, 23 of whom - as detailed in study field notes – discussed their main reason for taking part in the

study as being to ‘give something back’, ‘help others’, ‘make their own contribution’ or similar, during their first home visit.

The relationship between nurse and patient also appeared to be a tool in recruiting. As detailed in field notes, when present during a recruitment call by one of the nurses, I overheard the nurse asked the patient if they ‘could do me a wee favour’. The patient consented to be contacted by the researcher.

(4) Participant information

Recruitment nurses discussed how recruitment conversations began with a general ‘chat’ then a ‘brief’ synopsis of the study and request for consent to be contacted:

N1: … ‘the reason I’m phoning is to ask you I you would like to take part in this study’ and then I explained who you were and what you were doing… I didn’t give them an awful lot of information about what you were doing… I told them it was about their physical activity and that that would be getting monitored, but I didn’t give them much more information than that so… We just basically told them that, was it ok for you to get in touch with them and you would explain what the study was about. And really that was all we were getting was their consent for you to…

Recruitment nurses did not ask about participant SOC during recruitment calls. When asked, the nurses said they did not use the word ‘feasibility’ nor routinely highlight that the study was being undertaken as part of PhD research. On more than one occasion during initial home visits, I was asked if I was a nurse.

d. Is the randomisation procedure and RCT methodology acceptable to participants?

Table 11: *Group Allocation (mean ± SD)**

	Intervention (n=16)		Control (n=26)	
	CRC-S (n=8)	Partner (n=8)	CRC-S (n=13)	Partner (n=13)
I fully understood that I would be randomised to either Group A (PA consultation) or Group B (no PA consultation	4.6 (0.5)	4.4 (0.7)	4.5 (0.5)	4.8 (0.4)
I was satisfied with the way I was allocated to the group I was in	4.6 (0.5)	4.5 (0.5)	4.5 (0.5)	4.8 (0.4)
I was happy with the group I was in	4.6 (0.5)	4.6 (0.5)	4.4 (0.5)	4.8 (0.4)

*score range 1-5 (1-Strongly disagree; 2-Disagree;3-Neutral;4-Agree; 5-Strongly agree)

As detailed in Table 11 above, participants in both intervention arms reported fully understanding the randomisation procedure, feeling satisfied with the way in which the groups were allocated and being happy with the group to which they were allocated.

e. Do participants comply with accelerometer data collection and is this a suitable method of PA data collection for CRC-Cs in a future RCT?

Table 12 presents detailed data on accelerometer wear-time by all participants during the trial.

On average, CRC-Ss in the intervention group recorded 10 periods of accelerometer wear time and 10-11 periods of non-wear time across all 3 time points, the most wear-periods of all the groups. At baseline, the average period of wear time was 607.7 minutes (10.1 hours); this decreased to an average of 574.7 minutes (9.6 hours) at T1 and rose slightly to 583.9 minutes (9.7 hours) at T2. Average non-wear periods were relatively consistent across all 3 time points, at around 6.5 hours.

The data indicates that partners in both the intervention and control groups were more compliant with accelerometer wear, with wear periods and non-wear periods more closely consistent with the seven wear periods and seven non-wear-periods expected from a week's requested use (see Chapter Seven). Partners in

Table 12: *Accelerometer Feasibility Results*

		Intervention Group			Control Group		
		T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S							
Accelerometer wear periods:	mean (± SD)	9.9 (2.5)	10.9 (3.3)	10.2 (3.1)	10.2 (4.5)	9.1 (3.4)	8.7 (3.2)
	minimum	7	7	6	5	7	6
	maximum	16	18	15	20	19	17
Accelerometer non-wear periods:	mean (± SD)	10.2 (2.6)	11 (3.1)	10.6 (2.8)	10.8 (4.6)	9.7 (3.6)	9.3 (3.3)
	minimum	7	8	7	6	7	7
	maximum	16	17	16	21	20	18
Minutes of wear periods:	mean (± SD)	607.7 (200.9)	574.7 (150.9)	583.9 (172.8)	663.8 (221.7)	648.1 (182.3)	711.1 (137.2)
	minimum	268.5	319.88	326.9	289.4	262.7	491.4
	maximum	932.3	859.8	892.9	990.4	918.28	871.1
Minutes of non-wear periods:	mean (± SD)	392.6 (106.1)	383.9 (102.6)	410.1 (108.5)	387.9 (135.4)	441.1 (112.8)	465.9 (159.9)
	minimum	268.9	254.1	255.93	112.8	215.4	95.9
	maximum	599.9	524.1	570.6	563.9	567.8	640.9
Partners							
Accelerometer wear periods:	mean (± SD)	8.9 (2.4)	9.1 (3.7)	7.6 (1.8)	7.5 (1.3)	7.3 (1.4)	7.8 (3.2)
	minimum	5	6	3	6	5	1
	maximum	16	19	10	10	10	13
Accelerometer non-wear periods:	mean (± SD)	9.6 (2.5)	9.7 (3.8)	7.7 (1.7)	8.1 (1.3)	8.0 (1.4)	8.3 (3.0)
	minimum	6	6	4	6	6	2
	maximum	17	20	11	11	11	13
Minutes of wear periods:	mean (± SD)	625.2 (118.6)	684.2 (190.7)	688.1 (136.1)	747.1 (139.4)	708.0 (188.8)	709.5 (171.2)
	minimum	359.3	435.7	497.4	547.7	405.6	392.9
	maximum	794.1	945	926.9	964.6	993	995.3
Minutes of non-wear periods:	mean (± SD)	448.9 (108.1)	458.2 (148.8)	568.0 (235.1)	465.4 (65.8)	484.3 (79.0)	559.9 (315.4)
	minimum	254.8	90	340	356.5	345.3	339.2
	maximum	697.7	672.3	1239.2	542.2	583.2	1532

the intervention group recorded an average of 8.9, 9.1 and 7.6 days of wear periods and an average of 9.6, 9.7 and 7.7 days of non-wear periods at T0, T1 and T2 respectively. This suggests that at T2, partners in the intervention group were wearing the accelerometers as requested, for 7 full days during waking hours. Partners in the control group appear to have worn the accelerometers as requested at all 3 time points, recording an average of 7.5, 7.3 and 7.8 wear periods and 8.1, 8.0 and 8.3 non-wear periods at T0, T1 and T2 respectively. Further, partners in the control group also have the lowest average standard deviation in wear and non-wear periods.

Partners also recorded longer wear periods than CRC-Ss in both intervention arms, with the exception of CRC-Ss in the control group at T2, who recorded an extra 2 minutes on average. At T1 for example, CRC-Ss in the intervention group recorded the lowest average minutes of wear periods across all groups and time points, at 574.7 minutes (9.6 hours). In comparison, the highest average minutes of wear periods were recorded by partners in the control group (747.1 minutes [12.5 hours]). Partners in the control group recorded the highest average minutes of wear periods of all groups at each time point.

Analysis of participant evaluation sheets shows that, overall, participants reported being neutral as to whether or not they found the accelerometers easy and comfortable to use (see Table 13). However, there is a relatively large standard deviation in responses (0.7, and 1.0; 0.9 and 1.4, for CRC-Ss and partners in intervention and control arms respectively), indicating that, for some, the accelerometers were not comfortable. Five of the 29 CRC-Ss had stoma bags. Study field notes detail the discomfort expressed by three of these participants regarding use of the accelerometer and four participants reported this directly in the comments space on evaluation sheets. For example:

[Accelerometer] Belts slipped down or too tight around tummy (my cancer scar). Not comfortable.

- S01-Int

I disliked the accelerometer; found it uncomfortable to wear either under or over clothes. Did persist though.

- S02- Int

Also, one participant spoke of her discomfort when wearing the device owing to the location of her surgical scar. Both CRC-Ss and partners in the intervention and control arms did not find the accelerometer interfered with their daily tasks (2.0, 1.8; 2.4, 1.8 respectively).

Table 13: Data collection tools (mean±SD)

	Intervention (n=16)		Control (n=26)	
	CRC-S (n=8)	Partner (n=8)	CRC-S (n=13)	Partner(n=13)
The accelerometer was comfortable to wear	3.3 (0.7)	3.8 (1.0)	3.5 (0.9)	3.4 (1.4)
The accelerometer interfered with my daily tasks	2.0 (0.8)	1.8 (0.5)	2.4 (1.2)	1.8 (0.8)

*score range 1-5 (1-Strongly disagree; 2-Disagree;3-Neutral;4-Agree; 5-Strongly agree)

f. What are the completion and attrition rates for key outcome data during the trial?

AND

g. Are self-report outcome measures acceptable and feasible as methods to measure efficacy of the intervention in a definitive trial?

Table 14 details the total valid datasets (completion rate) and missing datasets (attrition rate) for each outcome measure in each intervention arm of the trial. Datasets that had complete data for all three time points were considered valid. Overall, there were 45 valid accelerometer datasets, of a possible 58. Therefore, 77.6% of participants wore the accelerometer for at least four consecutive days at each of the three time points in the study. 86.7% of both CRC-S and partners in the intervention group provided valid datasets during the study. Missing data was higher in the control group than in the intervention group. However, researcher error in initialising the accelerometers meant that two accelerometer datasets were missing at two separate time points – both times for CRC-Ss in the control group. Also, one device malfunctioned at one time point for a partner in the control group. Therefore, it is possible that had these devices recorded, those participant datasets would have been valid and included in analysis. This would bring the total number of valid datasets to 48 (82.8%).

Table 14: *Valid datasets*

	Intervention Group (n = 30)			Control Group (n = 28)		
	CRC-S (n = 15)	**Partner** (n =15)	**Total (n = 30)**	**CRC-S** (n = 14)	**Partner** (n = 14)	**Total (n = 28)**
PHYSICAL ACTIVITY						
Accelerometer						
Valid datasets	13 (86.7)	13 (86.7)	26 (86.7)	9 (64.3)	10 (71.4)	19 (67.9)
Missing	2 (13.3)	2 (13.3)	4 (13.3)	5 (35.7)	4 (28.6)	9 (32.1)
IPAQ: n (%)						
Valid datasets	11 (73.3)	12 (80.0)	23 (76.7)	11 (78.6)	13 (92.9)	24 (85.7)
Missing	4 (26.7)	3 (20.0)	7 (23.3)	3 (21.4)	1 (7.1)	4 (14.3)
MENTAL WELL-BEING						
Hospital Anxiety and Depression Scale (HADS): n (%)						
Valid datasets	10 (66.7)	9 (60)	19 (63.3)	12 (85.7)	11 (78.6)	23 (82.1)
Missing	5 (33.3)	6 (40)	11 (36.7)	2 (14.3)	3 (21.4)	5 (17.9)
Fear of Cancer Recurrence Inventory (FCRI): n (%)						
Valid datasets	12 (80)	n/a	12 (80)	13 (92.9)	n/a	13 (92.9)
Missing	3 (20)	n/a	3 (20)	1 (7.1)	n/a	1 (7.1)
PSYCHOSOCIAL TTM VARIABLES						
General Self-Efficacy (GSE): n (%)						
Valid datasets	12 (80)	13 (86.7)	25 (83.3)	13 (92.9)	12 (85.7)	25 (89.3)
Missing	3 (20)	2 (13.3)	5 (16.7)	1 (7.1)	2 (14.3)	3 (10.7)
Self-efficacy for PA: n (%)						
Valid datasets	8 (53.3)	9 (60.0)	17 (56.7)	12 (85.7)	12 (85.7)	24 (85.7)
Missing	7 (46.7)	6 (40.0)	13 (43.3)	2 (14.3)	2 (14.3)	4 (14.3)
Processes of Change: n (%)						
Valid datasets	7 (46.7)	8 (53.3)	15 (50.0)	9 (64.3)	9 (64.3)	18 (64.3)
Missing	8 (53.3)	7 (46.7)	15 (50.0)	5 (35.7)	5 (35.7)	10 (35.7)
Decisional Balance: n (%)						
Valid datasets	11 (73.3)	9 (60.0)	20 (66.7)	13 (92.9)	13 (92.9)	26 (92.9)
Missing	4 (26.7)	6 (40.0)	10 (33.3)	1 (7.1)	1 (7.1)	2 (7.1)
RELATIONSHIPS: n (%)						
Valid relationship questionnaires	14 (93.3)	13 (86.7)	27 (90)	14 (100)	14 (100)	28 (100)
Missing	1 (6.7)	2 (13.3)	3 (10)	0 (0)	0 (0)	0 (0)
QUALITY OF LIFE						
FACT-G and FACT-C: n (%)						
Valid datasets	12 (80)	n/a	12 (80)	12 (85.7)	n/a	12 (85.7)
Missing	3 (20)	n/a	3 (20)	2 (14.3)	n/a	2 (14.3)
WHOBREF: n (%)						
Valid datasets	n/a	11 (73.3)		n/a	12 (85.7)	
Missing	n/a	4 (26.7)		n/a	2 (14.3)	

*Outcome data at all 3 time points

None of the missing accelerometer data was due to absolute non-compliance (i.e., not wearing the monitor at all). Rather, missing data occurred due to partial

non-compliance (i.e., the monitor was not worn enough to meet the criteria for valid wear days [see results for Objective 1e above]).

Completion of the self-report PA measure was 73.3% for CRC-Ss in the intervention group and slightly higher for CRC-Cs in the control group, at 78.6%. Completion of partner self-reported PA was high, with 80% and 92.9% valid IPAQ datasets in the intervention and control groups respectively.

Completion rates for the HADS were notably lower in the intervention group than the control and had the second lowest completion rate of all the self-report measures. 66.7% of CRC-Ss and 60% of partners in the intervention group had valid datasets for this measure, compared to 85.7% of CRC-Ss and 78.6% of partners in the control group. However, completion rates for the second measure of mental well-being in CRC-Ss – Fear of Cancer Recurrence – were higher, at 80% for both intervention and control groups.

Completion rates for measures of SE were higher for GSE than for SE for PA – particularly for both CRC-Ss and partners in the intervention group. There was a total completion rate of 83.3% in the intervention group and 89.3% in the control group for GSE. However, total completion rate for GSE for PA in the intervention group was 56.7%, compared to 85.7% in the control.

Completion rate for the self-report relationship measure was very high across both groups. 90% of the intervention group and 100% of the control group had valid datasets for this outcome.

Completion rates for self-report QOL measures were high for both CRC-Ss and partners in both groups, although slightly lower for partners in the intervention group. 80% of CRC-Ss in the intervention group and 85.7% of CRC-Ss in the control group had valid datasets for FACT-G and FACT-C instruments. 73.3% of partners in the intervention group had valid datasets for the WHOBREF instrument, compared to 85.7% of partners in the control group.

The questionnaire booklet included instruments to assess Processes of Change and Decisional Balance. These outcomes were rescinded from analysis as I felt they were not relevant to assessment of trial feasibility or indicative effectiveness and were out with the remit and objectives of the pilot study. This study was not measuring the constructs of the TTM.

Participant responses to items pertaining to the questionnaire booklet in the evaluation form can be found in Table 15. Overall, participants agreed that the questionnaires were easy to complete (4.1, 4.2, 3.9, 4.4). However, the standard deviation for this question ranged from just over 0.5 to 1.0 in the intervention and control arms respectively, indicating that some participants found the questionnaires more difficult to complete. There was a larger standard deviation in responses to the item 'The questionnaires were time consuming'. Although overall response was neutral or close to neutral (2.9, 2.6, 3.1, 2.9), standard deviation ranged from 0.8 to 1.2, indicating that some participants did find the questionnaire booklet and instruments time consuming. Further, participant comments on the evaluation form expressed dissatisfaction with the questionnaires/booklet:

Silly questionnaires where the options given did not reflect what we wanted to say. Endless repetition of very similar questions. Badly worded!

-P01-Con

Some of the questions were ambiguous and some answers were therefore contradictory

-S03-Con

I did feel many of the questions were the same or very similar

-S01-Int

Questionnaires need to be more carefully worded or explicit

-P02-Int

Cut out extraneous sheets of questions – some seem to have been imported (uncritically) from other (American?) sources'

-S04-Int

The worksheets need to be thoroughly re-vamped because completing them – with so much not applicable to me – was often rather boring!

-S05-Int

Slightly simplify the questionnaire in parts

-P03-Int

The questionnaire options didn't reflect what we thought – a general criticism of multi-choice questionnaires.

-P04-Int

Sometimes I was asked the same question more than once in different categories.

-S06-Con

Table 15: Data collection tools (mean±SD)

	Intervention (n=16)		Control (n=26)	
	CRC-S (n=8)	**Partner (n=8)**	**CRC-S (n=13)**	**Partner(n=13)**
The questionnaires were easy to complete	4.1(0.6)	4.2 (0.6)	3.9 (0.9)	4.4 (0.8)
The questionnaires were time consuming	2.9 (0.8)	2.6 (1.0)	3.1 (1.0)	2.9 (1.2)
Standing on the weighing scale was inconvenient	1.6 (0.9)	1.6 (0.5)	1.9 (1.2)	1.6 (0.8)

*score range 1-5 (1-Strongly disagree; 2-Disagree;3-Neutral;4-Agree; 5-Strongly agree)

h. Are data collection and monitoring procedures feasible?

Table 16 presents participants' overall satisfaction with the study. Overall, participants reported being satisfied with the study and having enjoyed taking part. There is a suggestion that participants were slightly less satisfied with the amount of contact from the researcher, when comparing this score with other items. The same is true of items pertaining to preferring to be part of the study on one's own and preferring to be part of a study that takes place out with the home. For all three of these items, scores from participants in both groups still reflected general satisfaction in these areas (mean scores ranging from 1.5-2.2) just less so than others. From a participant standpoint, data collection and monitoring procedures appear feasible.

There was an overall data collection issue with regards to scheduling visits with participants and data collection. Visits could be difficult to arrange and often hard to keep to the time points of the study. As such, some couples' enrolment in

the study went beyond the six months (maximum 7.5 months). Further, ensuring that questionnaires and accelerometers were delivered and returned within the time scales of the protocol and with a single researcher was challenging. As a result, it was difficult to ensure that the questionnaire was completed before the accelerometer data was collected, subsequently to baseline visits.

Table 16: Overall satisfaction with the study (mean ± SD)

	Intervention (n=16)		**Control (n=26)**	
	CRC-S (n=8)	**Partner (n=8)**	**CRC-S (n=13)**	**Partner(n=13)**
I feel satisfied with the study	4.3 (0.5)	4.0 (0.5)	3.9 (0.9)	4.2 (0.7)
My involvement in the study was enjoyable	4.5 (0.5)	4.1 (0.6)	3.9 (0.9)	4.0 (0.9)
Arranging home-visits with the researcher was convenient for me	4.5 (0.8)	4.3 (0.7)	4.1 (0.6)	4.5 (0.5)
The amount of contact with/from the researcher was too frequent	1.9 (0.8)	1.9 (0.6)	2.1 (0.8)	1.7 (0.6)
I would prefer to be part of a study on my own, without my partner	1.7 (0.8)	2.0 (0.8)	2.2 (0.7)	1.5 (0.7)
I would prefer to be part of a study with another relative or friend	1.5 (0.8)	1.9 (0.8)	1.7 (0.6)	1.5 (0.5)
I would prefer to be part of a study that takes place out with my own home	1.6 (0.9)	1.5 (0.8)	1.9 (0.7)	1.4 (0.5)

*****score range 1-5 (1-Strongly disagree; 2-Disagree;3-Neutral;4-Agree; 5-Strongly agree)

8.2: *Objective Two*:

a. **Is it feasible and acceptable to conduct at home, face-to-face, joint consultations with CRC-Ss and their partners?**

b. **Is the content and structure of joint PA consultations suitable for delivery with CRC-Ss and their partners?**

The consultation was successfully arranged and delivered with all participants in the intervention group at both T0 and T1 (n=15 couples). Arranging the consultations at a time to suit both partners was easier with those couples who were retired and had more free time. Couples with whom arranging follow-up (T1) consultations at a suitable time was more difficult, often had a longer period than 12 weeks between consultations. The longest time between consultations was 18 weeks. Total time enrolled in the study therefore ranged from 6 to 7.5 months, depending on when follow-up consultations were arranged and final data collected. Participants appeared willing and motivated to book in the consultations and worked cooperatively with me to do so. The average length of one consultation was 55 minutes (minimum 35 minutes, maximum 90 minutes). Consultations were intended to last between 30-45 minutes.

At T0 and T1, full consultations were administered jointly with partners and CRC-Ss. Assessment of the consultation tapes using the observer checklist showed that overall, the consultations were delivered as intended and addressed most constituent parts (see Figure 11). However, there were a few components that were not covered or that were more difficult to traverse with two participants in the consultation. For example, components that involved more extensive discussion around PA behaviour, decisional balance and self-efficacy were more difficult to navigate with two people. Successful delivery of these parts of the consultation was often dependent on the interaction between the couples themselves during the consultation and the level of connection and rapport established with the researcher. This is discussed further below, in the results of the Situational Analysis. The components of the consultation that had variable outcome with regards to successful delivery were closely linked to the findings of the Situational Analysis.

Setting goals during the consultation was a component that was delivered successfully; in particular, the use of goal sheets for each participant was very well received. Every participant in the intervention group had a completed goal sheet at T0 and an updated goal sheet at T1. Participants engaged well with this part of the consultation and often assisted one another in setting goals (see below). However, post-study evaluation revealed that participants were dissatisfied with the lack of feedback regarding their goals:

Maybe a bit of feedback during the study/trial wouldn't have gone amiss
-P04-Int

I might have been better motivated if I'd known what the accelerometer recorded – did I reach my goals?
-S06-Int

Participants reported high levels of satisfaction with the consultations (see Table 17). The lowest reported score was partners' agreement that the consultations provided them with enough support to increase their PA (3.6). This score also had the highest standard deviation (0.9). One participant commented on the evaluation sheet: 'I am not sure how helpful exercise consultations would really be if faced with problems of bad prognosis, employment, finance or relationships'. However, a different partner commented that:

As a result of the study/consultations, I have taken part in two 10K and one 5K walks. I would never have done this prior to my involvement in the study. I'm looking forward to participating in more walks next year.

CRC-Ss reported the highest satisfaction levels with the consultation. In particular, the conduct of the study, the informal nature of the consultations and learning about PA were all noted in the evaluation sheets (see Appendices for full list of evaluation comments). Overall, participants reported liking taking part in the consultations with their partner.

Figure 11: ***Observer Checklist (consultation)***

COMPONENTS USED (n = 12)	Limited use/not at all	Satisfactory use	Very good use	Description
Set the scene	0	0	12	introductions, overview of consultation, reasons for attending
Assessed stage of change	0	0	12	Explained current activity guidelines
Assessed current activity status	0	0	12	Explained light, moderate and vigorous intensity activity and the different modes of activity.
Discussed past and present activities	0	3	9	Used prompts to discover client's likes and dislikes of activities they have done recently and in the past
Completed decisional balance	0	6	6	Encouraged client to explore pros and cons of change with discussion on overcoming cons. If appropriate, consultant provided information on benefits of physical activity. Client elicited own pros and cons for change and ways to overcome cons, consultant provided suggestions if appropriate.
Identified & addressed barriers to change	0	2	10	Client identified own barriers and elicited ways to overcome cons, consultant provided suggestions if appropriate.
Discrepancy between current activity status & guidelines	0	0	12	Explanation of current activity guidelines.
Identified opportunities for activity	0	0	12	Took into account client's likes and dislikes of past and present activities, barriers to activity, current lifestyle and needs.
Assessed and developed self-efficacy	8	2	2	Explored client's self-efficacy for physical activity and elicited ways to increase self-efficacy
Set Goals	0	0	12	SMARTER GOALS, Assessed confidence for goals, goals set by client with guidance by consultant.
Established support	2	7	3	Helped client to identify what support they need and how to receive this.
Relapse prevention	3	8	1	Encouraged client to identify high risk situations and develop ways to avoid or cope with these situations.

Table 17*: Satisfaction with the consultations (mean±SD) (Intervention group only)*

	CRC-S (n=8)	Partner (n=8)
The consultations provided me with enough support to increase my PA	4.3 (0.5)	3.6 (0.9)
The consultations were delivered well	4.5 (0.5)	4.5 (0.5)
The consultations were helpful	4.6 (0.5)	4.3 (0.5)
I liked having the consultations with my partner	4.1 (0.6)	4.0 (0.5)
I enjoyed the consultations	4.4 (0.5)	4.0 (0.8)

*****score range 1-5 (1-Strongly disagree; 2-Disagree;3-Neutral;4-Agree; 5-Strongly agree)

c. What are the key elements of joint PA consultations with CRC-Ss and their partners?

Figure 12 presents an Ordered Situational Map of joint PA consultations with CRC-Ss and their partners. The map displays the key elements that emerged from the SA of the consultations. The map shows who and what the main influences were during the consultations, who and what were important and what elements 'made a difference' during the consultations (see Chapter 7). Discussion of each element and relational analysis of the map in its entirety is out with the bounds of this study and constitutes a full research project in itself. As previously mentioned, my objectives are concerned with elements relevant to feasibility; therefore I primarily focus on these. I have selected a number of key elements to highlight, which are pertinent to intervention feasibility assessment (note - underlined text corresponds to underlined elements on the map).

<u>Research participants</u>

One of the key findings of the SA was the importance of the individual human actors in the consultation: the CRC-Ss, their partner *and* the researcher. The

Figure 12*: Ordered Situational Map of PA consultations with CRC-Ss and their partners*

INDIVIDUAL HUMAN ELEMENTS/ACTORS

Research participants: CRC-Ss, partners; researcher; CRC nurses; hospital physicians; GP; family and friends; neighbours; colleagues

COLLECTIVE HUMAN ELEMENTS/ACTORS

Hospital; universities; church; the government; the NHS; research bodies; PA research; PA and CRC research; cancer survival as health topic; health behaviour as a discipline

DISCURSIVE CONSTRUCTIONS OF INDIVIDUAL AND/OR COLLECTIVE HUMAN ACTORS

Perceived capacity for PA/PA behaviour change; gender stereotyping – marital 'roles'; excuses for not carrying out PA; a different a past – how things 'used to be'; the idea of unchangeable fixed human nature/personality and/or behavioural habits; the notion of PA as time-consuming; the PA narrative; idea of rejuvenation/reinvention; feelings of post-operative/treatment 'stagnation'; researcher as navigator of consultation; idea of PA as embarrassing; PA as unenjoyable; risk perceptions; fear of death; notion of Deception by study participants; infantilising of CRC-S – patient as child, partner as caretaker; being too old for PA

POLITICAL/ECONOMIC ELEMENTS

Health policy and PA guidelines; money and finances

TEMPORAL ELEMENTS

Age; cancer trajectory; change over time in personality; time taken up by PA; the past and reminiscence; change in marital relationship over time; change in health over time; monitoring PA outcome/progress; future PA goals; time-management; pace of modern life and urban environment

MAJOR ISSUES/DEBATES (USUALLY CONTESTED)

What it means to be physically active; idea of being stuck in one's ways; perceived negative consequences of partaking in PA

RELATED DISCOURSES (HISTORICAL/NARRATIVE AND/OR VISUAL)

Participant personal history; participant PA history

NONHUMAN ELEMENTS/ACTANTS

PA guidelines; CRC surgery/treatment; Interdependence Theory; idea of 'teachable' moment'; TTM of behaviour change; previous PA research evidence; data collection instruments; accelerometer; other health behaviours – smoking, diet; CRC diagnosis; public transport; cars; PA paraphernalia; pets; money; the intervention; PA goals; pain; social support; medication; individual physical activities; comorbidities; barriers to PA; weather; shared PA behaviour; shared lifestyle

IMPLICATED/SILENT ACTORS/ACTANTS

CRC-Ss; partners of CRC-Ss; family and friends of CRC-Ss

DISCURSIVE CONSTRUCTIONS OF NONHUMAN ACTANTS

Health benefits of PA; implications of PA for CRC survival; PA behaviour change as a process; measurability of PA; measurability of other health outcomes; stages of PA behaviour change; shared health behaviours; marital 'roles'; cancer diagnosis as 'teachable moment'; positive and negative health behaviours; PA change as part of study/intervention; idea of measurable progress/results; psychosocial constructions of PA and behaviour change process

SOCIOCULTURAL/SYMBOLIC ELEMENTS

Age; gender; social class; education; religion; marital status; 'husband'; 'wife'

SPATIAL ELEMENTS

Participants' home; access to green space; the outdoors; urban milieu; Greater Glasgow and Clyde; location of participants' homes; space and temporal elements (feeling 'hemmed in and 'old' in a 'fast-paced' world); social isolation; the space of consultation as an abstract or metaphorical space; design/structure of participants' homes (eg. house, flat, with garden or without); distance from amenities and PA opportunities

OTHER KEY ELEMENTS

Language and dialogue*; behaviour reinforcement between partners (positive or otherwise; dyadic/triadic interaction and dynamic; motivation; participant perception of and bond with researcher; rapport; resistance to change (by one or both partners); consultation as therapeutic opportunity; role of researcher; partner anxiety; researcher as mediator; reminiscence; consultation transition

Figure 13: Consultation structure, dynamic, language and dialogue

Use of 'I' or 'we'; closed vs. open discussion; participants working as couple vs. working as individuals; talking as one; interrupting; stilted vs. flowing discussion; partner overwhelming CRC-S; defensiveness; problem-solving – working through a narrative; participants navigating consultation; partner and researcher navigating consultation/working together; partner as dismissive; storytelling; mirroring; humour; self-deprecation; prompting; 'teasing out' by researcher; hurrying the consultation; placating researcher; supportive language; competitiveness; transition through consultation; PA-wary vs. PA-involved; engaging beyond the consultation vs. engaging within structure alone.

significance of these human actors was very closely linked to elements of consultation structure, dynamic, language and dialogue. These elements underpinned the consultation and as such have been presented as a separate map sub-section in Figure 13. These elements of the analysis were mostly associated with the interactive and conversational mechanisms through which the consultations took place. It is not a specific objective of this study to assess these mechanisms. However, these elements were found to influence and relate closely to other parts of the map and feasibility assessment, as they demonstrate how joint PA consultations may work; therefore these elements will be discussed, where relevant, throughout the results.

The researcher

The role of the researcher in this situation was an important influence on the consultations. As an individual human actor, not only was I the researcher in the situation, but for participants analysis emphasised that I was also a PA consultant, a student, a mediator, an outsider - or third party – and a supervisor. One participant, for example, referred to me as 'the boss', positioning me in a superior role. All of these different roles and the consequent perception and positioning of the researcher within the situation made an important difference to the dynamic and interaction during the consultations:

R: So you feel that you could do 20 minutes brisk walking a few times a week?

CRC-S: If you say so boss!

This was also closely linked to sociocultural elements on the map, such as age, gender and education. I was a young, educated woman carrying out an intervention

in participants' homes, as part of a doctoral project. This played an important part in how participants viewed me, the rapport established and the bond I developed with them. Primarily, my role as a young, female student was the most prominent. This perception appeared to influence positively the connection established between researcher and participants, engage participants in the consultation and foster an attachment in participants towards the researcher, whom they wanted to 'help' by taking part in the study and the consultations. This has important implications for feasibility.

Some participants however, were unclear about my background and some initially thought that I was a nurse. I found this misconception of the identity of the researcher to detrimentally impact on the dynamic within the consultation; partners were disappointed and became detached; the consultations functional and brief.

Research participants: partners

The presence of the partners in the consultations is integral to feasibility assessment and was one of the most important elements to arise from the Situational Analysis. There were various presentations of the role that the partner played during the consultation and a number of corresponding elements that contributed to this. In some couples, for example, partners operated together with CRC-Ss during the intervention, working through each component of the consultation with them as a team. These couples took control of the consultation and engaged well with and were supportive of one another throughout. This occurred both for couples who decided to carry out PA and set goals together and for couples who preferred to do this independently. This type of mutual interaction was also reflected in consultation structure, language and dialogue. During these consultations, for example, couples would individually refer to themselves as 'we' when talking to the researcher, there was little lengthy or extended dialogue by the researcher and minimal input by the researcher; these couples motivated one another:

CRC-S: Well, there's a lot I could do to exercise. I've got pretty bad legs, you know, and I should really do exercise, although I do find it difficult walking…

P: Because you've had to stop sometimes just to… I tend to forget about his legs. I like walking, you know, when we go anywhere I like to walk.

CRC-S: You make a point of getting the highest incline! You know, it forces me up there you know…

P: Because I get breathless too, come on, don't exaggerate. But we haven't done a great deal of exercise, activity, this past while… I think the most exercise we get is going up and down the stairs just now

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CRC-S: We enjoy getting out and walking around… We don't take the car. We get the bus or the train which means you are being active all the time.

P: And you know if the weather is nice we go places and walk around and that sort of thing.

CRC-S: We go down to the coast and we have a walk along the front.

This type of interaction also took one of two forms; an interaction where the primary focus is on the PA behaviour and health of the CRC-S, or an interaction where the focus is on the PA behaviour of both the CRC-S and the partner. Most often however, increased focus was placed on the CRC-S, with the partner in a supportive role. Figure 14 presents a case extract of dialogue between one couple, which demonstrates the elements highlighted above.

Within other couples, the partner worked independently of the CRC-S and the consultation was much more rigid around the structure, with more input and steering by the researcher. Rapport and dynamic in these instances was less well established and consultations tended to be shorter in length, despite effectively consisting of two individual consultations carried out at the same time, as opposed to a joint consultation.

Another role that partners were found to play during the consultation was that of caretaker. For the majority of CRC-Ss, their partner was their main emotional and physical support from diagnosis, through surgery and treatment, to enrolment in the study. Partners had taken care of their spouses and some still lived within that role. This impacted on the interaction during some of the consultations, when partners would stifle and overwhelm CRC-Ss and dominate the discussion and interaction. This also related very closely to infantilising of the CRC-S by their partner during the consultation, when partners would sometimes refer to them and talk about them to the researcher as though they were not present, or discuss issues

on their behalf. In this context, the CRC-S was not highly engaged in the consultation:

R: [addressing CRC-S] Do you have facilities at work that might help [to change after walking to work]?

P: That would be a very ideal situation and it wouldn't work. They don't have facilities for you to get changed and do what you've got to do. They don't have it.
CRC-S: I suppose there is that…

R: Is there anywhere at work to walk…

P: But he walks as part of his job. You do patrol.

CRC-S: Yes, there is that I suppose, but…

P: You could be patrolling for ten minutes each time.

CRC-S: Yes, but…

P: That's a fair amount of time

R: Okay…

P: [referring to earlier suggestion of swimming by CRC-S] But I don't think going for a swim in your break times is feasible. For a start, you don't know when your break is.

There was also an important relationship with this element and partner anxiety and risk perception about PA, following CRC. A number of partners were concerned about their spouse partaking in PA, in case it would cause further illness, cancer recurrence or stress. The cancer diagnosis was still very much a presence for some partners:

R: You were saying your confidence has taken a bit of a dive?

CRC-S: Yes... I haven't done much [PA] at all.

P: That may be my fault. I've encouraged you to take rests… I thought I was going to lose you… I want you to recover properly…because not every day does he feel good. He still gets pain. You've got to take that into consideration.

Anxiety about loss of time with their spouse is reflected by a partner in another consultation:

P: You don't want to take up golf now.

CRC-S: No, no. My sport's well, a bit different now.

F: If you played golf I would never see you.

CRC-S: That's true. No, it's ok – I won't take up golf.

Interdependence Theory and shared PA behaviour

Analysis revealed that, although couples may share similar PA behaviour, as measured by SOC and PA outcome results, they do not necessarily behave similarly. Even couples who appeared more cohesive or interdependent, found the idea of carrying out new PA or building on existing PA together as unimaginable, novel or even embarrassing:

P: If people saw we walked up together [to the shop], people would start talking about it [laughter]

Further, analysis uncovered that, as well as facilitating the components of the consultation and behaviour change, interdependence between couples and the presence of a partner could also be detrimental to the process and content of the consultations. Shared SOC and PA behaviour was found in some instances to have the effect of reinforcing unhealthy practices. The presence of a partner had the effect of rationalising and legitimising unhealthy PA behaviour. Couples would engage in individual and/or shared PA narratives, through which they processed their PA behaviour. These narratives were found to be mutually reinforcing and an impediment to focused and productive consultations:

R: What about the route to church – is that the only route?

CRC-S: Oh, I could make it longer but that goes against reason so I don't do that. You can make it longer. You can make it as long as you want to but I always think straight lines are the shortest distance between 2 points and so are the best…

P: Time would be an issue. I would walk to church, but I take my mum, who is 83 and lives at the end of the road – so you can't really say 'well I'm walking to church and you can walk if you like!' Well at work I do a wee walk up the hill in the morning – 5 minutes – and 5 minutes back, which is downhill…

CRC-S: It's still a third of your time

Another couple, highlighting also links with age and the past:

CRC-S: When you get to our age… the position we're in at the moment… we are kind of hemmed in

P: There are no activities that we could actually do… years ago we used to

This element is also inextricably linked to SOC. Couples who were collectively more resistant to PA behaviour change and less engaged in the consultation, did not possess the characteristics of people in a contemplative SOC. This is reflected in the quantitative results and has important implications for trial and intervention feasibility:

P: I could do a bit more walking but that's basically all, you know, because I feel quite happy with the way I am

CRC-S: I am happy with the way my life is going on, so I don't see why you tell me to change it to be honest

Then there were those who were not interdependent at all and engaged separately, chose separate physical activities and goals and did not use one another for support:

R: So, thinking about being more physically active, what would be the pros for you of becoming more active? Individually or together.

CRC-S: Oh we would never do it together!... No, no, no

The consultation that followed was very separate, for each partner.

Consultation as therapeutic opportunity

This is an important feasibility element arising from the SA. The consultation became a therapeutic opportunity for some couples, who appeared disinterested in the actual consultation process and structure and more interested in opportunistically discussing other concerns and personal circumstances. Predominantly, these participants veered into discussion about their cancer diagnosis, the impact and emotional effects it has had on their lives and other comorbidities that they wished to discuss. This was related to the age, SOC and comorbidities of the participants; the consultation was often a therapeutic opportunity for older couples, at the pre-contemplative SOC and who had additional health issues:

P: [unsolicited] The flu.

CRC-S: When I found out I had cancer – I had a chest infection. Now I've had them a couple of times since, but the doctor said when your system's down, you catch it.

P: Oh chest infections, worst I've ever seen.
CRC-S: You wouldn't realise.

P: …and the bed's shaking, feet, everything. And then I get a row off the doctor because I'm doing the wrong thing – giving him hot water bottles because he's freezing. He says no, your immune system is over-heating. It's just your body seems cold so I haven't to give him…that was the wrong thing to do.

M: So that could hit you at any time at our age. Even your age. Anybody.

P: Pain in your side…

Dyad and triad

Within the consultation, analysis revealed the presence of the couple as a dyad, for whom the intervention was intended and directed towards and corresponding to the rationale of joint consultations. Analysis also revealed however, that the presence and role of the researcher as PA consultant and motivator, made the intervention triadic in nature, within which three people were partaking in the consultation; the intervention was not merely dyadic with a separate interventionist. The researcher/interventionist was part of the fabric of the consultation and not external to or simply delivering it. This was an important element, which was reflected in the various ways in which participants and the researcher worked through the consultations. In some instances, it was the participants navigating the consultation, together as couple, with guidance from the researcher; during other consultations it was the partner and researcher working together through the consultation, to motivate the CRC-S. There were few instances of the CRC-S and researcher working together to motivate the partner; in these instances the focus of the consultations veered naturally either towards the CRC-S, with the partner in a supportive role, or to the couple as a dyad or single unit – working through behaviour change together.

Figure 14: Dialogue case extract

P: Why don't you make it at least 3 days a week, even if you don't feel like going out – just walk up to Bishopbriggs, for a brisk walk; realistic for you…

CRC-S: How far is that?

P: Quarter of a mile

CRC-S: Behave yourself!

P: Half a mile.

CRC-S: Behave yourself!

P:… if you think it's realistic for this week…

CRC-S: I know, I know – realistic for this week; walk half a mile, three quarters of a mile

P: A 20-minute walk?

CRC-S: Aye, rather than in mileage

P: If it's longer, all well and good

CRC-S: Yes, yes

P: So a 20-twenty minute walk?

CRC-S: a 20-minute walk each day, weather permitting

P: No – will you do that each day? Would that not be ambitious? Because that means starting tomorrow… Wouldn't it be better to say a 20-minute walk on 3 days to start?

CRC-S: Aye, yer right.

P: Three days a week you'll walk 20 minutes through the park, yes?

CRC-S: Why don't we do it together then?

P: We could do Saturday as well.

PA goals

PA goals and goal sheets were received well and were a very important element in the consultations. Whether participants chose to carry out activities together or apart, all participants engaged with setting 4 week, 3 and 6 month goals. The goals sheets represented measureable progress, which analysis showed was important to participants.

This element was again closely linked to how interdependently and cohesively partners interacted with one another. Again, whether goals or chosen activities themselves were shared or not, the process of setting the goals was assisted by couples who encouraged one another and interacted supportively:

CRC-S: Well, the reason I'm saying four 20 minute walks, is its 10 minutes there and 10 minutes back. So if we did 4 walks to the village…

P: Walk to the village in 10 minutes?

CRC-S: I'm saying 10 minutes there and 10 back, but it might take us longer…

P: … Maybe we take the car down to the big car park and walk from there to church and back… take the car half way at first…and there would be a wee bit of an incline.

CRC-S: Aye.

'Post-operative stagnation'

For me, I have actually stagnated over the last couple of years since my operation. I really haven't done much at all. I was quite happy; I was very positive going in for that operation… but after that confidence just took a dive.

-CRC-S

This element is an important finding for feasibility assessment. A number of CRC-Ss referred to their diagnosis, surgery and treatment during the consultation. For some, these experiences instilled a sense of 'rejuvenation' and 'reinvention'; for others, this trajectory had had a detrimental impact on their PA behaviour and motivation. This was very closely related to time since diagnosis and treatment; those who felt more 'stagnated' were most often those for whom a longer time had passed since diagnosis.

Barriers

The SA also shed light on the barriers to PA for CRC-Ss and their partners. Although this was directly asked of participants during the consultation, the consultation process itself drew out further information on what might help or hinder PA behaviour change amongst this population. These included spatial elements such as distance from green space and amenities, feeling 'hemmed in' and feelings of fear or anxiety.

8.3: *Objective 3*:

To evaluate the <u>indicative effectiveness</u> of the intervention on key outcome domains by answering the following questions:

a. What is the preliminary impact of joint PA consultations on the PA levels of CRC-Ss and their partners?

Objective measurement of PA – Accelerometers:

1. Accelerometer output results can be found in Table 18. The average total activity count per day decreased over time for every group, except CRC-Ss in the control group.

The highest average total activity count per day for CRC-Ss in the intervention group was 865,032.3 counts, recorded at baseline. This count decreased to 817727.6 at T1 then rose again at T2 to 844485.6; 20546.7 counts lower than at baseline. Partners in the intervention group recorded markedly lower activity counts than CRC-Ss and remained fairly consistent over time, with average total activity counts of 745835.4 and 748474.0 at T0 and T1 and a slight dip to 730555.5 at T2. These results from the raw accelerometer data therefore indicate that PA levels decreased over time from baseline for CRC-Ss in the intervention group and that there was no, or very little, change for partners in the same group. It is worth noting however, that CRC-Ss in the intervention group recorded the highest average total activity counts per day of all groups at each time point. With a baseline count of 865032.3 (the highest recorded count), this was 84008.5 counts higher than the average baseline count of CRC-Ss in the control group, 268834.1 counts higher than the lowest recorded average total activity count per day (recorded by partners in the control group at T1) and 33780.4 counts higher than the that of the control group at T2. The average total count per day of CRC-Ss in the intervention group at T2 was 844485.6, compared to 831251.9 in the control group.

CRC-Ss in the control group however, did increase their average total activity count per day between T0 and T2. Between T0 and T1, the average count decreased from 781023.8 to 697098.9; however, average count increased at T2 to 831251.9. Conversely, partners in the control group recorded the largest drop in average total activity counts between T0 and T2 of all groups. At T0, partners in the control group recorded an average count of 754374.8. This dropped to 596198.2 at

T1 then rose to 645053.6 at T2 – 109321.2 counts lower than at T0. These results from the raw accelerometer data therefore indicate that PA levels increased over time from baseline to T2 for CRC-Ss in the control group but decreased over time for partners in the same group.

CRC-Ss recorded higher activity counts than partners in both groups at all time points.

2. Accelerometer output results show that CRC-Ss in the intervention group recorded increased time spent in moderate intensity PA from T0 to T1 and from T1 to T2. At T0, CRC-Ss in the intervention group spent an average of 95.2 minutes in moderate intensity activity per week, rising to 115.5 minutes at T1 and 119.1 minutes at T2. However, despite an increase over time, the average minutes spent in moderate intensity activity per week by CRC-Ss in the intervention group did not meet the PA guidelines of 150 minutes per day.

Average minutes spent in light and lifestyle PA intensities by CRC-Ss in the intervention group decreased over time from T0 to T2, from 1419.8 to 1214.2 and from 383.9 to 337.1 respectively. Average minutes spent in vigorous intensity PA was nominal at each time point.

Partners in the intervention group also recorded an increase in average minutes spent in moderate intensity activity between T0 and T1, from 109.6 to 140.9 – 9.1 minutes short of meeting the PA guidelines. However, there was a considerable drop between T1 and T2, to an average of 80.9 minutes – 28.7 minutes less than at T0.

Partners in the intervention group recorded a similar increase in average minutes spent in light and lifestyle PA intensities between T0 and T1 (from 1359.8 and 373.5 to 1485.2 and 481.5 respectively), followed by a decrease between T1 and T2, to fewer than at T0 (1270.6 and 347.1 minutes). Again, data recorded for average time spent in vigorous intensity activity was nominal.

CRC-Ss in the control group recorded the largest decrease over time in average minutes spent in moderate intensity activity, from 238.9 at T0 to 141.2 at T2. This group therefore regressed from comfortably meeting to being below the PA guidelines. The standard deviation however, was higher than the mean, indicating considerably large spread in the data. Average minutes per week spent in light and

lifestyle intensity activities also decreased over time amongst CRC-Ss in the control group. Between T0 and T1, average time spent in light intensity activity decreased by 123.5 minutes and by a further 122.9 minutes between T1 and T2. Lifestyle intensity activity decreased by 44.8 and 75.9 minutes between T0 and T1 and T1 and T2 respectively - a total of 120.7 average minutes per week. This group recorded zero minutes spent in vigorous or very vigorous intensity activities at all time points.

Partners in the control group were the only participants to record average minutes per week of moderate intensity activity that met the PA guidelines and did so at all time points, despite a decrease over time from 233.3 minutes at T0 to 204.6 minutes at T2. Partners in this group spent less time in light intensity activity than CRC-Ss and this time also decreased over time, from 1393.9 average minutes per week at T0 to 1109.4 at T2. Similarly, average lifestyle minutes also decreased, from 480.6 to 378.7 at T0 and T2 respectively.

Recorded data on average minutes spent in sedentary intensity activity per week remained fairly consistent across all groups and accounted for the most time spent in any intensity activity.

Standard deviation in results for CRC-Ss and partners in both groups - for average total activity count per day and average minutes spent in different PA intensities per week - was very high (see Table 14). It is important to note therefore, in assessing these results, that the data for accelerometer outcomes was spread across a wide range of values. Also, there is greater standard deviation for results of average minutes spent in moderate intensity activity per week than for minutes spent in other intensity activities. This suggests that there was greater variance in change over time in minutes spent in moderate intensity activity than minutes spent in light and lifestyle intensity activities.

Table 18: *Accelerometer Output Results*

	Intervention Group			Control Group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S						
Total activity count per day: mean (± SD)	865032.3 (157426.8)	817727.6 (229482.8)	844485.6 (176101.9)	781023.8 (177331.1)	697098.9 (110944.2)	831251.9 (238730.7)
Minutes spent in different PA intensities per week						
Sedentary: mean (± SD)	3903.5 (918.3)	4213.5 (588.7)	3921.2 (754.9)	3951.6 (1185.5)	3695.3 (612.4)	3643.3 (1707.8)
Light: mean (± SD)	1419.8 (499.5)	1231.5 (392.1)	1214.2 (395.9)	1466.1 (352.3)	1342.6 (306.9)	1219.7 (552.5)
Lifestyle: mean (± SD)	383.9 (164.5)	325.1 (154.5)	337.1 (216.9)	441.6 (220.1)	396.8 (181.0)	320.9 (167.1)
Moderate: mean (± SD)	95.2 (53.1)	115.5 (69.0)	119.1 (70.3)	238.9 (215.6)	263.4 (277.2)	141.2 (153.2)
Vigorous: mean (± SD)	1.2 (4.2)	0.5 (1.1)	4.4 (12.4)	0 (0)	0 (0)	0 (0)
Very vigorous: mean (± SD)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Partners						
Total activity count per day: mean (± SD)	745835.4 (201736.2)	748474.0 (181971.5)	730555.5 (265226.2)	754374.8 (219082.8)	596198.2 (146073.5)	645053.6 (225215.4)
Minutes spent in different PA intensities per week						
Sedentary: mean (± SD)	3504.4 (824.4)	3657.2 (1042.8)	3420.3 (957.6)	3327.3 (828.9)	3263.1 (1058.5)	3380.4 (1309.5)
Light: mean (± SD)	1359.8 (397.3)	1485.2 (445.9)	1270.6 (451.9)	1393.9 (339.6)	1173.8 (295.1)	1109.4 (398.9)
Lifestyle: mean (± SD)	373.5 (271.1)	481.5 (256.7)	347.1 (193.8)	480.6 (288.8)	352.9 (242.1)	378.7 (325.7)
Moderate: mean (± SD)	109.6 (123.1)	140.9 (154.7)	80.9 (79.0)	233.3 (258.1)	191.1 (151.5)	204.6 (151.8)
Vigorous: mean (± SD)	0.92 (2.6)	2.3 (5.7)	2.8 (9.7)	1.4 (3.8)	2.6 (8.2)	1.3 (4.1)
Very vigorous: mean (± SD)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Self-reported PA – IPAQ

Table 19: Self-reported PA - IPAQ

	Intervention Group			Control Group		
Category of PA (n (%))	**T0**	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S						
Low	3 (27.3)	1 (9.1)	0 (0.0)	0 (100)	1 (9.1)	0 (0.0)
Moderate	6 (54.5)	5 (45.5)	6 (54.5)	7 (63.6)	5 (45.5)	5 (45.6)
High	2 (18.2)	5 (45.5)	5 (45.5)	4 (36.4)	5 (45.5)	6 (54.5)
Partners						
Low	5 (41.7)	3 (25.0)	1 (8.3)	1 (7.7)	0 (0)	0 (0.0)
Moderate	2 (16.7)	6 (50.0)	7 (58.3)	8 (61.5)	6 (46.2)	5 (38.5)
High	5 (41.7)	3 (25.0)	4 (33.3)	4 (30.8)	7 (53.8)	8 (61.5)

Results from the self-report IPAQ questionnaires show that at T0, the majority of CRC-Ss in the intervention group reported PA levels that categorised them as moderately active in the previous week. Six participants (54%) fell into the 'moderate' category of PA, three (27.3%) into the 'low' category and two (18.2%) into the 'high' category. At T1, there was an increase in participants categorised as having 'high' PA, to five (45.5%) but a slight drop in those reporting PA that would categorise them as 'moderate', to five (45.5%). Two (18.2%) less CRC-Ss in the intervention group were classified as having 'low' levels of PA at T1. AT T2, no CRC-Ss in the intervention group were reporting low levels of PA in the previous week; six (54.5%) reported moderate levels of PA and there was no change from T1 in those reporting high PA levels (45.5%). These results suggest that over time, there was no change in the moderate PA levels of CRC-Ss in the intervention group but that there was a decrease in low levels of PA and an increase in high levels of PA.

In contrast, fewer partners in the intervention group reported moderate levels of PA at T0 – only two (16.7%) compared to six (54.5%) of CRC-Ss. However, at T1 this number increases to 6 (50%) and to seven (58.3%) at T2. Partners in the intervention group therefore, report greater increases in PA level over time than CRC-Ss. Partners in the intervention group however, did report higher levels of low and vigorous PA at T0; five (41.7%) of partners fell into the 'low' category of PA and the same number into the 'high' category. Those with low levels of PA at T2 reduced to one (8.3%) at T2 and those with high levels to 4 (33.3%). Therefore, self-reported PA results in the intervention group show increased levels of moderate PA and

decreased levels of low PA for partners. Further by T2, results show similar PA levels between CRC-Ss and partners.

Both CRC-Ss and partners in the control group reported higher levels of PA than their counterparts in the intervention group. No CRC-Ss and only one partner (7.7%) reported low level PA at T0. Seven (63.6%) CRC-Ss were categorised as having been moderately active in the previous week and 4 (36.4%) as highly active at T0. Over time, those categorised as moderately active decreased to five (45.5%) at T1 and T2. Those reporting high levels of PA however, increased over time, to five (45.5%) at T1 and to six (54.5%) at T2. Similarly, eight (61.5%) partners in the control group were categorised as moderately active at T0 and four (30.8%) as highly active. Again, numbers reporting moderate PA decreased over time and those reporting high PA increased, from eight (61.5%) at T0 to 5 (38.5%) at T2 and four (30.8%) at T0 to eight (61.5%) at T2 respectively. These results suggest that PA amongst both CRC-Ss and partners in the control group changed over time from moderate to higher levels.

Self-reported SOC

Table 20: *Self-reported SOC for PA*

	Intervention Group			Control Group		
Self-reported SOC for PA: n (%)	**T0**	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S						
Not starting to think about doing more PA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (14.3)
Starting to think about doing more PA	9 (60.0)	4 (26.7)	2 (13.3)	6 (50.0)	3 (21.4)	0 (0)
Being physically active occasionally, but not regularly	4 (26.7)	6 (40.0)	8 (53.3)	3 (21.4)	6 (42.9)	6 (42.9)
Being regularly physically active for less than 6 months	1 (6.7)	4 (26.7)	2 (13.3)	2 (14.3)	2 (14.3)	1 (7.1)
Being regularly physically active for longer than 6 months	1 (6.7)	1 (6.7)	1 (6.7)	3 (14.3)	3 (21.4)	5 (35.7)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Total	15 (100)	15 (100)	15 (100)	14 (100)	14 (100)	14 (100)
Partners						
Not starting to think about doing more PA	2 (13.3)	3 (20.0)	0 (0)	0 (0)	0 (0)	4 (28.6)
Starting to think about doing more PA	4 (26.7)	0 (0)	2 (13.3)	1 (7.1)	3 (21.4)	3 (21.4)
Being physically active occasionally, but not regularly	6 (40.0)	8 (53.3)	6 (40.0)	4 (28.6)	6 (42.9)	2 (14.3)
Being regularly physically active for less than 6 months	1 (6.7)	3 (20.0)	5 (33.3)	1 (7.1)	0 (0)	1 (7.1)
Being regularly physically active for longer than 6 months	2 (13.3)	0 (0)	2 (13.3)	7 (50.0)	5 (35.7)	4 (28.6)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Total	15 (100)	15 (100)	15 (100)	14 (100)	14 (100)	14 (100)

Results suggest that SOC for PA improved over time for CRC-Ss in the intervention on group. At baseline, all CRC-Ss in the intervention group reported that they were starting to think about doing more PA or were already physically active. 9 (60%) of CRC-Ss in this group said they were 'starting to think about doing more PA' and 4 (26.7%) said they were 'physically active occasionally, but not regularly'. 1 CRC-S reported 'being regularly physically active for less than 6 months' and 1 (6.7%) said they were 'being regularly physically active for longer than 6 months'. In the intervention group over time, there was a decrease in the number of CRC-reporting that they were' starting to think about doing more PA', to 4 (26.7%) at T1 and 2 (13.3%) at T2. This was accompanied by an increase in those who reported 'being regularly physically active occasionally, but not regularly', to 6 (40%) at T1 and 8 (53.3%) at T2. There was an increase in the intervention group at T1 in CRC-Ss who reported 'being regularly physically active for less than 6 months', to 4 (26.7%), however this dropped to only 2 (13.3%) at T2. There was no increase in the number of CRC-Ss in the intervention group reporting 'being regularly physically active for more than 6 months'.

Results also show an improvement in SOC for PA amongst partners in the intervention group. At baseline and at T1, 2 (13.3%) and 3 (20%) partners, respectively, reported 'not starting to think about doing more PA'. By T2, this number was 0. At T0, 4 partners (26.7%) were 'starting to think about doing more PA', compared to 0 at T1. This was accompanied by an increase from T0 to T1 in the number of partners reporting 'being physically active occasionally, but not regularly', from 6 (40%) to 8(53.3) and an increase in partners reporting 'being regularly physically active for less than 6 months', from 1 (6.7%) to 3 (20%). At T2, there were less partners reporting 'being physically active occasionally, but not regularly', but a rise by 2 (13.3%) in those reporting 'being regularly active for less than 6 months' and in those reporting 'being regularly physically active for longer than 6 months'. These results suggest positive transition across the stages of exercise change for both CRC-Ss and partners in the intervention group. However, the majority of participants remained at the SOC of 'being regularly physically active occasionally, but not regularly' and would therefore be presumed not to be meeting the PA guidelines. CRC-Ss and partners in the control group had higher numbers than their counterparts in the intervention group who reported the highest SOC for

PA at baseline; 3 (21.4%) of CRC-Ss and 7 (50%) of partners in the control group reported 'being physically active for more than 6 months'. The majority of CRC-Ss in the control group however, reported 'starting to think about doing more PA' at a baseline (6[50%]). This number decreased at T1 to 3 (21.4%) and then to 0 at T2. At the same time, reporting of 'being physically active occasionally, but not regularly' increased from 3 (21.4%) at T0 to 6 (42.9%) at T1 and T2. Only 2 (14.3%) of CRC-Ss reported 'being physically active regularly for less than six months' at T0 and T1, dropping to 1 (7.1%) at T2; however, there was also an increase to 5 (35.7%) in CRC-Ss reporting 'being regularly physically active for longer than 6 months'. These results suggest possible forward progression through the SOC for PA for some CRC-Ss in the control group.

Although 50% of partners in the control group reported the highest SOC at baseline, there was an increase from 4 (28.6%) to 6 (42.9%) in reporting of being 'being physically active occasionally, but not regularly' from T0 to T2. This decreased however, to 2 (14.3%) at T2. This was accompanied by a decrease from T0 to T2 in the number of partners reporting 'being physically active for more than 6 months', to 5 (35.7%) at T1 and 4 (28.6%) at T2. There was also an increase over time in those reporting 'not starting to think about doing more PA' and 'starting to thinking about doing more PA', from 0 to 4 (28.6%) and 1 to 3(21.4%) respectively, from T0 to T2. These results suggest regression in the SOC for PA of partners in the control group.

b. What is the preliminary impact of joint PA consultations on the mental well-being of CRC-Ss and their partners?

Table 21: *Mental Well-being – HADS results*

	Intervention Group			Control Group		
	T0	T1	T2	T0	T1	T2
CRC-S						
Anxiety score (range 0-21): mean ± SD	2.9 (3.9)	2.1 (3.2)	1.8 (3.1)	5.1 (3.9)	5.3 (3.7)	5.1 (3.6)
Depression score (range 0-21): mean ± SD	2.4 (2.8)	2.6 (2.5)	2.7 (3.9)	2.8 (1.8)	3.2 (2.8)	2.2 (2.3)
Total score (range 0-42): mean ± SD	5.3 (6.4)	4.7 (5.1)	4.5 (5.9)	7.8 (5.5)	8.4 (5.9)	7.4 (5.5)
Partners						
Anxiety score (range 0-21): mean ± SD	3.8 (3.0)	2.3 (1.7)	2.7 (2.4)	5.4 (3.6)	5 (3.4)	5.3 (3.9)
Depression score (range 0-21): mean ± SD	2.1 (1.8)	1.9 (1.7)	2.1 (1.5)	2.5 (3.0)	2.5 (2.9)	2.7 (3.5)
Total score (range 0-42): mean ± SD	5.9 (4.2)	4.2 (2.5)	4.8 (3.7)	7.8 (6.0)	7.5 (5.7)	8.0 (7.0)

Across all groups and participants, no mild or severe depression or anxiety scores were recorded at baseline or follow up (ie. depression anxiety subscale scores were all below 8 and total scores below 16). However, there was a 1.1 point decrease in anxiety scores for CRC-Ss *and* partners in the intervention group over time between T0 and T2, from 2.9 to 1.8 and 3.8 to 2.7 respectively.

There was no change over time in anxiety scores for CRC-Ss or partners in the control group. However, both CRC-Ss and partners in the control group reported higher anxiety scores than the intervention group at each time point.

There was no or nominal change reported in depression subscale scores across all groups and participants at each time point.

Table 22*: FCRI results*

	Intervention Group			Control Group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-Ss						
FCRI Total score (range 0-168): mean ± SD	47.7 (37.5)	48.2 (36.3)	36.4 (38.2)	47.6(24.7)	43.2(28.1)	41.5(25.5)

Table 22 presents FCRI results for CRC-Ss. Mean baseline scores for FCR were similar for the intervention and control group, at 47.7 and 47.6 respectively (28% of the maximum score for FCR). Both scores had a large standard deviation, although this was 13 points higher for the intervention group, at 37.5 (22.3% of the maximum score), compared to 24.7 in the control group (14.7% of the maximum score). Over time, both groups showed a decrease in mean FCR scores, although this was slightly higher for the intervention group (6.7% decrease from T0 to T2) than the control group (3.8% decrease from T0 to T2). However, the standard deviation at T2 for the intervention group was higher than the mean total score (38.2 compared to 36.4), indicating large variance of result. Further, standard deviation of mean scores was lower in the control at each time point than in the intervention group (12.8, 8.2 and 12.7 lower at T0, T1 and T2 respectively).

c. What is the preliminary impact of joint PA consultations on the QOL of CRC-Ss and their partners?

As denoted in Table 23, CRC-Ss in both the intervention and control group reported high QOL at each time point. FACT-C total score in the intervention group was marginally higher than the control group at T0 (116.0 compared to 113.1) and increased slightly over time to T2 by 3 points (119.4) where the control group dropped by one point (112.6). However, this difference was nominal. Across all FACT-C subgroups, CRC-Ss in both intervention arms report high and similar QOL. Partners in both intervention and control groups also reported consistently high and broadly similar QOL across each of the domains in the WHO-BREF at each time point (see Table 20). There was nominal change over time. Standard deviation for this outcome was also relatively low across all time points, suggesting less distribution in the QOL data for partners. The largest change over time was in Domain One (physical health) scores for partners in the intervention group; the average scores were 15.4 (s.d. 2.5) and 16.3 (2.9) at T0 and T2 respectively. Again, this difference is slight. These results suggest that there was no change over time in the QOL of CRC-Ss nor partners.

d. What is the preliminary impact of joint PA consultations on the psychosocial variables of the TTM (SE, POC and DB) in CRC-Ss and their partners?

General Self-Efficacy

Table 24: *General Self-Efficacy (GSE) Results*

	Intervention Group			Control Group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S GSE Total Score (range 10 to 40): mean (± SD)	33.1 (4.17)	34.3 (4.0)	35.8 (8.8)	30.9 (4.3)	30.0 (4.8)	33.9 (9.6)
Partners GSE Total Score (range 10 to 40): mean (± SD)	30.4 (2.9)	31.5 (5.2)	31.0 (5.5)	31.0 (3.4)	30.7 (4.5)	32.5 (4.0)

At T0, GSE of CRC-Ss in the intervention group was quite high (33.1) with a standard deviation lower than those for many of the other intervention outcomes

Table 23: *Quality of Life Results*

	Intervention Group			Control Group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S (FACT-G and FACT-C)						
FACT-G Physical Well-being (range 0-28): mean ± SD	23.75 (4.69)	24.75 (3.55)	24.38 (3.85)	23.53 (4.35)	23.85 (5.05)	24.32 (4.24)
FACT-G Social/Family Well-being (range 0-28): mean ± SD	27.17 (2.50)	25.39 (3.38)	25.41 (2.80)	24.06 (4.62)	23.57 (3.14)	23.43 (4.21)
FACT-G Emotional Well-being (range 0-24): mean ± SD	20.58 (3.09)	20.33 (2.10)	21.33 (3.37)	21.00 (2.41)	20.67 (2.64)	21.25 (2.67)
FACT-G Functional Well-being (range 0-28): mean ± SD	23.83 (6.09)	24.50 (4.50)	25.58 (3.83)	23.08 (4.91)	21.80 (5.72)	22.08 (5.16)
FACT-G Total Score (range 0-108): mean ± SD	95.33 (11.41)	94.97 (10.98)	96.70 (9.13)	91.67 (12.46)	89.88 (14.22)	91.08 (13.57)
FACT-C Subscale (range 0-28): mean ± SD	20.64 (5.39)	22.78 (5.21)	22.74 (4.10)	21.42 (4.48)	22.15 (4.59)	21.53 (4.69)
FACT-C Total Score (range 0-136): mean ± SD	115.97 (13.46)	117.75 (13.38)	119.44 (10.40)	113.09 (16.22)	112.04 (18.40)	112.62 (16.85)
Partners (WHO-BREF)						
Domain 1 (range 4-20): mean ± SD	15.4 (2.5)	16.1 (2.2)	16.3 (2.9)	16.8 (1.8)	17.0 (2.1)	17.0 (2.5)
Domain 2 (range 4-20): mean ± SD	16.4 (1.5)	16.4 (1.5)	16.1 (2.3)	16.6 (1.7)	16.2 (2.3)	15.9 (2.4)
Domain 3 (range 4-20): mean ± SD	16.2 (2.0)	16.5 (1.9)	17.6 (2.0)	17.2 (2.4)	16.9 (2.9)	17.2 (2.8)
Domain 4 (range 4-20): mean ± SD	16.9 (1.6)	17.0 (1.5)	17.1 (2.4)	18.1 (1.5)	18.0 (2.1)	17.5 (2.4)
Q1 - How would you rate your quality of life? (range 1-5): mean ±SD	4.5 (0.5)	4.4 (0.5)	4.6 (0.5)	4.5 (0.5)	4.5 (0.7)	4.3 (0.9)
Q2 - How satisfied are you with your health? (range 1-5): mean ± SD	3.9 (0.8)	4.2 (0.8)	4.3 (0.8)	4.2 (0.8)	4.1 (0.8)	4.0 (1.1)

(4.17). Over time, there was a small increase in this score, to 34.3 at T1 and 35.8 at T2. However, the standard deviation also increased at T2, to 8.8. Data was thus more widely distributed than at T0.

CRC-Ss in the control group reported a similar small increase over time in GSE and standard deviation. At T0, GSE was 30.9 (SD 4.3); this increased to 33.9 (SD 9.6). CRC-Ss in the control group reported the highest increase in GSE over time of all the groups (and the highest standard deviation, at T2).

Partners in the intervention group reported slightly lower GSE at T0 than CRC-Ss (30.4) and showed nominal change over time in scores (31.5 at T1 and 31.0 at T2). However, the gap between partner and CRC-Ss total GSE score widened over time, as CRC-Ss total score increased slightly. At T0 the difference in scores was 2.7; this increased to 4.8 at T2.

Processes of Change

Table 25: *Processes of Change Results*

	Intervention Group			Control Group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S						
Experiential processes (range 0-5): mean ± SD	2.0 (0.5)	2.2 (0.7)	2.0 (0.7)	2.1 (1.1)	2.2 (1.0)	2.0 (1.0)
Behavioural processes (range 0-5): mean ± SD	1.9 (0.6)	2.4 (0.9)	2.3 (0.7)	2.2 (0.7)	2.3 (0.8)	2.2 (0.9)
Partners						
Experiential processes (range 0-5): mean ± SD	1.8 (0.5)	1.8 (0.6)	1.9 (0.6)	1.9 (0.6)	1.9 (0.7)	2.0 (1.0)
Behavioural processes (range 0-5): mean ± SD	1.7 (0.7)	1.9 (0.7)	2.0 (0.6)	2.1 (0.5)	2.1 (0.5)	2.2 (0.7)

*range (1='never'; 2 and 3 = 'occasionally'; 4 and 5 = 'repeatedly')

Table 25 presents POC results. Participant use of experiential and behavioural POC was low and remained consistently low at each time point and across intervention and participant groups. At no time point did any grouping report a mean of higher than the 'occasional' use of the POC. CRC-Ss reported slightly higher utilisation of the POC than partners at each time point. At T0, T1 and T2, CRC-Ss in the

intervention group reported a mean of 2.0, 2.2 and 2.0 respectively for experiential processes, compared to 1.8, 1.8 and 1.9 for partners; a mean result indicating no use of the POC by this group. At T1, CRC-Ss in the intervention group also reported a slight increase in the use of behavioural processes and the standard deviation (0.9) takes some responses above 'occasionally' to 'repeatedly'. At each time point however, CRC-Ss in the control group report slightly higher use of behavioural processes at each time point, although there was no mean change over time. Partners in the control group also reported slightly higher means at each time point and no change over time, compared to lower mean scores for partners in the intervention group. However, although mean POC scores were low overall, both CRC-Ss and partners did report a slight increase in behavioural POC over time (from 1.9 to 2.4 and 2.3, and 1.7 to 1.9 and 2.0 respectively).

Decisional Balance

Table 26: *Decisional Balance Results*

	Intervention Group			Control Group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S						
Pros total score (range 0-15): mean ± SD	11.0 (2.4)	9.9 (4.2)	9.7 (3.4)	9.8 (2.0)	9.6 (3.2)	9.5 (3.1)
Cons total score (range 0-15): mean ± SD	7.6 (2.0)	5.8 (2.0)	5.5 (2.7)	6.1 (1.3)	5.3 (2.3)	5.7 (1.9)
Partners						
Pros total score (range 0-15): mean ± SD	10.1 (2.2)	8.6 (3.3)	8.5 (1.9)	9.7 (3.0)	9.7 (3.4)	8.7 (3.2)
Cons total score (range 0-15): mean ± SD	6.4 (2.8)	6.1 (2.1)	7.5 (2.2)	6.3 (2.2)	6.0 (2.1)	7.5 (2.8)

Table 26 presents DB results. CRC-Ss and partners in the control group had the highest mean baseline total scores for pros for engaging in PA (11.0 and 10.1 respectively). These scores decreased over time, to 9.7 and 5.5 respectively at T2, indicating a reduction in the perceptions of pros for PA. Standard deviation at T1 and T2 however, was 4.2 (28% of maximum score) and the highest of all DB result standard deviations, indicating large variance in outcome. Mean total scores for

cons of engaging in PA were lower than the pros at baseline and also decreased over time for CRC-Ss in the intervention group, from 7.6 to 5.8 and 5.5. There was a slight increase in the mean con total score for partners in the intervention group, from 6.4 and 7.5 from baseline to T2. Total pros scores for CRC-Ss and partners in the control group remained moderately high and consistent over time (between 9.5 and 9.8 and 8.7 and 9.7 respectively). Partners in the control group were the only group to demonstrate any increase in mean score for cons for PA over time, from 6.3 to 7.5.

e. What is the preliminary impact of joint PA consultations on relationship quality and support between CRC-Ss and their partners?

Table 27: *Quality of Relationship Results*

	Intervention Group			Control Group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
CRC-S						
Relationship total score (range 6-24): mean (±SD)	13.9 (1.7)	14.7 (3.3)	14.2 (2.1)	13.7 (1.4)	13.9 (1.8)	13.8 (1.2)
Relationship support for PA (range 3-21): mean (± SD)	8.5 (4.9)	10.9 (6.1)	10.5 (6.4)	12.8 (5.3)	13.2 (6.2)	11.2 (5.5)
Partners						
Relationship total score (range 6-24): mean (±SD)	14.6 (1.6)	14.2 (1.6)	14.9 (1.4)	14.3 (1.6)	14.0 (2.1)	13.8 (1.8)
Relationship support for PA (range 3-21): mean (± SD)	11.5 (6.4)	10.4 (6.1)	8.8 (5.0)	12.1 (7.0)	11.5 (5.6)	12.2 (7.2)

CRC-Ss and partners in the intervention group reported broadly similar relationship scores at each time point. The range of possible scores was 6-24; at T0 total relationship scores were relatively low, at 13.9 and 14.6 for CRC-Ss and partners respectively. Standard deviation was low, indicating that results were not largely distributed around the mean. Over time, change in total scores for both CRC-Ss and partners in the intervention group were nominal; results at T2 were 14.2 and 14.9 for CRC-Ss and partners respectively.

Very similar results were conveyed in the control group. At T0, total relationship score was 13.7 and 14.3 for CRC-Ss and partners respectively; at T2, results were 13.8 for both. Again, standard deviation was low, suggesting low distribution.

Relationship support for PA was low, particularly in the intervention group. CRC-Ss in the intervention group did report an increase over time in relationship support for PA, from 8.5 at T0 to 10.9 at T1 and 10.5 at T2. There was a large standard deviation in results however, much more so than for relationship total score. The standard deviation was 4.9 at T0, 6.1 at T1 and 6.4 at T2.

Conversely, partners in the intervention group reported a decline in relationship support for PA. Although at T0 partners reported slightly higher support for PA than CRC-Ss (11.5 versus 8.5), this decreased over time, to 10.4 at T1 and 8.8 at T2. Again, standard deviation was high (6.4, 6.1 and 5.0 at T0, T1 and T2 respectively).

Both CRC-Ss and partners in the control group reported higher support for PA at T0 than the intervention group (12.8 and 12.1 respectively). There was little change over time in partner scores, which remained broadly the same. CRC-Ss in the control group reported a nominal increase of 0.4 from T0 to T1, then a drop of 2 to 11.2 at T2. Again however, this change was small and standard deviation of results – for both CRC-Ss and partners at all time points – was relatively high.

Chapter Nine: Discussion

CRC survival in Scotland has improved considerably over the past 40 years, with the 5-year relative survival rate for both men and women diagnosed with the disease having more than doubled from 29% to 60% (ISD Scotland, 2015). PA has been shown to improve CRC-specific and overall-survival amongst CRC-Ss, as well as positively impacting on numerous physical and psychosocial health outcomes (Je et al., 2013; Des Guetz et al., 2013; Speck et al., 2010; Lynch et al., 2016). Despite this, however, PA levels amongst CRC-Ss have been found to be suboptimal and there has been limited intervention research that has targeted the PA behaviour of this population. Further, there has been no intervention or feasibility research that has assessed the potential of joint interventions with CRC-Ss and their partners. Whether or not CRC-Ss can be successfully recruited to an RCT of a PA intervention, how best to initiate behaviour change and whether or not a partner could also be successfully included is uncertain. Therefore, as stated in Chapter One, this pilot study was designed to answer the following research questions:

- Is it feasible to conduct an RCT of a face-to-face PA intervention with CRC-Ss and their partners?

- Are joint PA consultations a feasible intervention for CRC-Ss and their partners?

- What is the likely impact of joint PA consultations on the PA levels and health outcomes of CRC-Ss and their partners?

In this chapter, I will describe and interpret the importance of the main findings of my pilot study and their contribution to the literature discussed in Chapters One and Two. I will discuss key findings, any new understanding arising from these findings and how this study has moved the above research questions forward. I will first summarise the main findings of Objectives 1-3, addressing

the implications of these results for PA intervention research with CRC-Ss. Where areas for future research are discussed, these are highlighted in bold and picked up again in Chapter Ten. I will then go on to identify study limitations and weaknesses and their relative importance in relation to interpretation of the results. Where relevant throughout the discussion, I highlight any limitations as they arise.

8.1: *Objective One: To evaluate the feasibility of trial and data collection methods*

The eligibility rate for the study was 55%; this is slightly lower than the 67% eligibility rate reported by Hubbard et al. (2016). 74.7% were not eligible because they did not meet the inclusion criteria of having a partner. Eligibility constraints emerged as a key theme salient to recruitment feasibility during interview with recruitment nurses. The nurses discussed finding the criteria of having a spouse or partner restrictive during the process of identifying eligible participants and exclusionary of CRC-Ss who would otherwise benefit from the intervention. Many of those excluded from the study were documented as living with or nearby another close relative or friend; this raises the question of why the intervention should not include a non-romantic partner who might live with or close enough to support CRC-Ss in PA behaviour change, especially when evidence suggests that not having a partner is negatively correlated with PA in cancer survivors (Van Putten et al., 2016). Research has demonstrated that social support can improve PA engagement in cancer survivors and can be sourced from various family, friends and members of the community (Barber et al., 2012, WHO, 2017), therefore incorporating alternative sources of support needs to be investigated. Further, including family and friends in the consultations could increase eligibility for a trial and reach higher numbers of CRC-Ss who could benefit from a PA intervention. Further, excluding those without a partner risks overlooking CRC-Ss who are socially isolated and creating inequality in opportunity and care.

There was a broad spread of participants across the range of time since completion of treatment, although the majority had completed treatment within the previous year (58.6%). Of these, 41.2% had completed treatment

within the previous six months and 58.8% within the following six months. This suggests that CRC-Ss who are closer to diagnosis and treatment are willing and able to take part in a PA intervention. This provides support for the teachable moment and the suggestion that proximity to diagnosis may be a factor in health behaviour change (Mullens et al., 2004; Demark-Wahnefried et al., 2005). It would have been helpful to have more detailed data on time since treatment within the first six months. Evidence from the SA and interview with colorectal nurses suggests that within the first six to eight weeks since treatment would be too soon for a PA intervention for many CRC-Ss. As one CRC-S said, they "couldn't do anything" during this time. Therefore, this study suggests that ≥2 months post-treatment is a feasible time to recruit CRC-Ss to a PA intervention study.

Consent and recruitment to the study was very successful; 64.5% of eligible participants were contacted by nurses about the study, of which 87.8% consented to be contacted by the researcher and 59.1% of those consented and were ultimately recruited and randomised (29 couples). This consent rate exceeds that of recent feasibility PA studies with CRC-Ss (Hubbard et al., 2016, consent rate 31%). As a result, 35.5% of identified eligible patients were not contacted about the study due to the target sample being achieved. Further, the target sample (30 couples) was successfully reached within 15 weeks of the beginning of recruitment. This result is encouraging and supportive of feasibility, especially given that this was a single-centre study and that research indicates 50% of RCTs fail to recruit their target number (Fletcher et al., 2012). These results also compare favourably with those of other feasibility intervention studies with CRC-Ss, including Sellar et al. (2014), who successfully recruited 40% of eligible participants to an exercise intervention over a 1 year period and Courneya et al. (2016), who recruited 273 CRC-Ss, from 42 sites, over a 6 year period, to a longitudinal PA study. Results also corroborate recent feasibility research carried out since the completion of my study that found CRC-Ss can be successfully recruited to behavioural intervention studies (Grimmett et al., 2015).

Successful recruitment could be reflective of the recruitment method adopted. Potential participants were contacted directly, first by the colorectal

nurses and then by the researcher; Grimmett et al. (2015) found study uptake to be higher with direct contact (72%) compared with letter contact (27%). During the post-study interview, it emerged that the nurse's close relationship with the CRC-Ss also appeared to play a significant part in the achievement of high consent and recruitment rates and was identified as one of four emergent recruitment themes. Nurses felt that the bond, rapport and history they had with their patients was fundamental to the recruitment process and appeared to utilise this connection to achieve consent. Further, nurses said that they contacted those eligible patients that they felt would be more likely to consent to being part of the study. This has important ethical and feasibility implications for a larger trial, regarding whether or not it is appropriate for colorectal nurses who were responsible for patient care to be recruiting to a trial and, if not, whether recruitment would prove as successful with alternative recruiters.

High recruitment was also found to be closely linked to the altruistic reasons that the majority of CRC-Ss described as being why they decided to take part in the study. 23 CRC-Ss reflected wanting to 'give something back' through participation in the trial; this echoes the findings of research on patients' willingness and reasons for participating in randomised controlled and other trials (Moorcraft et al., 2016; McCann et al., 2010). Altruistic motives for participation appeared confounded by the fact that the patients' medical caregivers during treatment were approaching them about the study; patients spoke very highly of the nursing staff and care they received and so wanted to participate to 'give something back' as a direct result of this relationship and care experience. Again, this raises ethical considerations regarding who is the most suitable person to contact CRC-Ss (former patients) about a research study.

Importantly, the partners of CRC-Ss were also successfully recruited to the study and appear motivated to take part in a PA intervention; only 3 partners of CRC-Ss contacted about the study refused to take part. This refutes evidence that enrolling couples to RCTs is notoriously difficult (Voils et al., 2011). Both CRC-Ss and their partners were willing and motivated to take part and 100% of those who consented to take part were successfully

randomised to intervention or control. Further, both partners reported being very satisfied with the way in which they were approached about, recruited to and randomised in the study, suggesting feasibility of this strategy in a future trial.

In addition to the nurse-CRC-S relationship and eligibility constraints, participant information issues and time constraints for nurses were found to have implications for the feasibility of the recruitment strategy. Nurses reported often carrying out recruitment out with their working hours due to lack of time and spending time during recruitment calls discussing issues pertinent to the patients' health and medical concerns. Despite this, they didn't feel that the recruitment process itself was overly time-consuming and therefore the recruitment strategy appeared to be feasible. Issues around the delivery of participant information at the point of first contact however, would need to be addressed in a future trial. Participants were not always fully informed as to the nature of the study they were being asked to partake in, nor to the credentials of the researcher. This was related to the relationship between nurses and CRC-Ss discussed above; nurses primarily utilised their connection with the CRC-s and engaged in a general 'chat' about the study during recruitment conversations, meaning that essential information was often not relayed to potential participants. **This has important implications for future research and recruitment methods, which should seek to refine this process and encourage compliance from recruiters.**

Retention of participants to the trial was optimal, at 100%. This suggests evidence of potential participant retention rates and is consistent with retention in recent feasibility studies with CRC-Ss (Hubbard et al., 2016; Grimmett et al., 2015). This provides strong support for a future RCT. However, although attrition in participants recruited to the trial may have been nil, high attrition and loss to follow-up in some key outcome data suggests that, while participants remained in the trial for the duration, they did not necessarily engage with all aspects of the process. Again, this corresponds with recent research by Hubbard et al. (2016), who found attrition over time in self-report outcomes to amount to 36.5% and 31% in objective PA measures (of 69% of datasets collected). In this study, loss to follow-up in outcome data

was highest for mental well-being measures of anxiety and depression (HADS) in the intervention group (36.7%) and overall (17.9%), self-reported PA (IPAQ) in the intervention group (23.3%) and self-efficacy for PA in the intervention group (43.3%). For all self-report data, attrition was higher in the intervention group than the control group, for both CRC-Ss and partners and higher amongst CRC-Ss than partners. The only exception was objective accelerometer data, for which attrition was higher in the control than the intervention group. However, as will be discussed below, attrition in accelerometer data was not due to complete non-compliance by participants, but rather due to partial non-compliance or monitor malfunction. Research suggests that attrition is higher for secondary outcomes as more focus is placed on primary outcome (Dumville et al, 2006). However, in this study, attrition is higher for self-report measures as opposed to objective measures (the proposed primary outcome for a future trial).

Grimmett et al., (2015) reported low attrition in a behavioural intervention study with CRC-S, at 14%. This suggests that specific components of this study could explain attrition. It is unclear however, if there was any attrition in outcome data and how this was processed by Grimmett et al. (2015), therefore similarities or otherwise between studies should be interpreted with caution.

Attrition in my data may reflect that selected outcomes or instruments are unacceptable to participants, a number of whom reported discontent with the content, relevance and/or length of the questionnaires. Results also indicate that participant burden could be an important reason for attrition in self-reported outcome data. A number of extraneous questionnaires were included in outcome measure booklets, such as POC and DB measures. These were not pertinent to outcome and the study objectives were not concerned with assessing the use of the constructs of the TTM in the consultation. Therefore, these additional scales made questionnaire completion more burdensome and time-consuming and could have contributed to the sense of irrelevance of measures. Attrition in data should also be considered within the context of the altruistic nature of participation in RCTs, as discussed above. Altruistic motives for participation in research are

not always sufficient – participants also have to be motivated to engage and comply with study protocol, therefore **establishing motive and interest in a PA behaviour change intervention study should be further incorporated into the recruitment procedure of future research.**

Overall however, drop-out from the trial was nil and results indicate that outcome measures are feasible; attrition was generally low given the sample size and only high for specific measures of anxiety and depression and PA. Modifications to the questionnaire booklet to make it less burdensome and more relevant however, are required. Also, barriers to completion of self-report measures of mental well-being and PA need to be investigated.

These results are very important findings for the feasibility of a future trial and highlight why feasibility research is so important. Future research may wish to investigate factors associated with attrition in data in PA intervention studies with CRC-Ss and strategies to overcome them.

Participants engaged well with the accelerometers and, overall, there was high compliance, particularly in the intervention group. Accelerometers were successfully collected from 100% of participants throughout the trial, indicating acceptability of use. This compares well with the 69% of accelerometers collected by Hubbard et al. (2016). There were also no instances of total non-compliance with the accelerometers, which also suggests this is an acceptable measure for CRC-Ss and their partners. There were 26 valid datasets out of 30 for the intervention group (86.7%) demonstrating that wear-time requirements were met and that participants wore the monitors as requested. Amongst the control group however, there were considerably more missing datasets, primarily as a result of partial non-compliance (ie. the monitor was not worn enough to meet wear-time requirements). There were 19 valid datasets out of 28 (67.9%) in the control group; 5 were missing from CRC-Ss and 4 from partners. The Hawthorn Effect dictates that participants in a control group are likely to alter the behaviour being observed in a trial, purely as a result of being observed, even though they are not receiving the intervention (McCambridge et al., 2014); however, these results suggest that participants in the control group were less inclined to comply with the objective measure of PA in this trial, possibly as a

result of not receiving the intervention. Therefore, The Hawthorn Effect was not evidenced in their engagement and behaviour. It should be noted however, that two instances of missing data from the control group were as a result of monitor malfunction.

Overall, of the 100% of monitors collected, there were 77.6% valid datasets and only 22.4% missing. This compares favourably with 31% of excluded data from 69% of accelerometers by Hubbard et al. (2016). As highlighted, there were failings with the accelerometers that meant that data was not recorded for some participants at certain time points; therefore their existing data would not have met the criteria for validity and would have been excluded from analysis. It is possible that, had the accelerometers not failed, these participants' data may have been valid.

Taking account of participant evaluation sheets, data collection problems and overall valid datasets, I am confident that accelerometers *are* a suitable means of PA data collection for CRC-Ss and would recommend that a future pilot of this study include accelerometers as the primary outcome measure. However, **further research is needed into the use of accelerometers amongst CRC-Ss who have stoma bags, as the small number of participants in this study who did have a stoma reported discomfort when using the device**. This may impact on the use of accelerometers during the study and therefore on overall results. Also, the use of the device with CRC-Ss who have recently completed surgery and/or treatment is problematic, as the site of surgical scarring could potentially be irritated by an accelerometer that is worn on the hip. Future studies should consider possible data collection using accelerometers that are worn on the arm or on the thigh. Wearing the device on the hip does provide the most accurate method of PA data collection (Rosenberger et al., 2013), however, studies that have used accelerometers on the arm or leg have also demonstrated reasonable validity and reliability (Shiroma et al., 2016; Montoye et al., 2016).

8.2: *Objective 2: To evaluate feasibility and acceptability of joint PA consultations*

Findings suggest that conducting home-based, joint PA consultations is feasible and acceptable to CRC-Ss and their partners. Compliance was 100%, with all 15 couples in the intervention group receiving two consultations, at baseline and T1. This corresponds to adherence evidenced in previous randomised controlled pilot studies, which was found to be 90% and above (Bourke et al., 2011; Sellar et al., 2014). My study protocol included interim telephone consultation catch-ups with participants, between T0 and T1 and T1 and T2. However, the telephone calls proved difficult to schedule, especially with both partners and one researcher. They were rescinded from the protocol early on. **Future studies should find solutions to this problem, as CRC-Ss have been shown to respond well to behavioural telephone interventions (Anderson et al., 2010). Overcoming this may require greater research capacity**.

Arranging consultations was successful, however there were variations in the length of time between consultations and, subsequently, follow-up outcome measures. The range of time in the study was between 6 and 7.5, months which could potentially confound outcome data in a larger trial. Estimated time for delivery of the intervention with two people also has to be adjusted, to anticipate longer consultations.

Assessment of the PA consultation tapes using the Observer Checklist showed that the intervention was well-received by participants and was successfully delivered as intended, addressing each component of the consultation with couples. However, the consultation often became two concurrent consultations rather than one joint one. Certain components, such as PA behaviour and decisional balance, were on occasions addressed for each participant individually in a parallel fashion, as opposed to addressing individual concerns within a collaborative interaction. This made the delivery of the consultation less fluid and potentially more time consuming. The dyadic and triadic dynamic within the consultation was found to influence this outcome. As PA consultations were developed for use with individuals,

modifications to structure may be needed to deliver the intervention with two (or more) people.

As has been found in previous research (Grimmett et al., 2015), the use of print materials was well-received. Participants found the goals sheets helpful in supporting their PA behaviour change and this modification to the consultations should be retained. PA goals and goal sheets were also an important element to arise from SA, as they represented measurable progress in PA behaviour for participants. **Incorporation of feedback on participant PA goals throughout the trial could be part of future protocol, as participants reported missing this from the intervention.** However, it is difficult to provide feedback without it potentially impacting on behaviour during the trial. If this were to be incorporated, a standardised approach across both study arms would be required; or communication with participants from trial outset that feedback will not be given until the end and why, could be considered.

Participants, especially CRC-Ss, reported good levels of satisfaction regarding the intervention; however some expressed concern that PA consultations may not be adequate in providing the level of support needed to increase PA levels. Inclusion of a partner was rated highly with regards to intervention satisfaction and therefore would appear to be acceptable. The presence of the partner is discussed further below.

SA of the intervention tapes revealed key elements of joint PA consultations pertinent to feasibility assessment, as well as providing an Ordered Situational Map of key elements of joint PA consultations with CRC-Ss and their partners, from which to build this intervention and future research (see Chapter Seven for SA methodology and Figure 12 for Ordered Situational Map). Notably for feasibility assessment and, perhaps expectedly, the three human actors in the consultation (CRC-S, partner and researcher), were found to be key elements in the intervention. Particularly important for feasibility was the presence of the partners. SA revealed partners to be a feasible inclusion in the intervention in terms of consultation process. Further analysis showed key elements that suggest the impact of the partner during the consultation to be variable. The assumption made when designing this study, was that partners

would be a source of social support and work together with CRC-Ss to facilitate and encourage PA behaviour change, as well as potentially engaging in positive PA behaviour change themselves. For some couples, this was the case; partners and CRC-Ss worked together and took control of the consultation. These couples were supportive of one another and directly impacted each other's PA decision-making. This corresponds with previously highlighted research that found direct impacts by partners on one another's CRC screening behaviour (Manne et al., 2012). Also, similarly to Barnett et al. (2013), couples supported one another to pursue increased PA even if they chose to take part in PA independently of one another. Spousal support, as discussed by Barnett et al. (2013), was integral for some couples engagement with and progress through the consultation and ultimate decision-making around uptake of PA.

Other couples worked less interactively and supportively with one another, in a parallel fashion within the consultation. The presence of a partner in these instances was still feasible, but altered the dynamic of the consultation, which became more formal and less supportive of behaviour change. Regardless of the role the partner played however, most often, the PA behaviour of the CRC-S became the main focus of the consultation. There was a sense in all consultations that they were intended for the CRC-Ss and not the partner. This could also have impacted on engagement by partners and the interaction between couples, therefore placement of the partner in the consultations needs to be better established in a future intervention.

Closely linked to this finding were non-human elements, or actants, pertinent to feasibility assessment of the consultations - Interdependence Theory and shared PA behaviour (non-human elements/actants include theoretical influences on the situation - see Chapter Eight). These key elements were anticipated as they were part of the theoretical rationale for the study and as such are important measures of feasibility. Postulation underlying the rationale of the study was that CRC-Ss and their partners were likely to share PA behaviour and that the consultations might facilitate mutually beneficial PA behaviour change in both CRC-S and partner, if

couples took part in the intervention together (see Chapter Three). Although this was the case for some couples, analysis found that shared health behaviour also had the effect of reinforcing unhealthy PA behaviour practices and generating a mutual resistance to change in others. This evidence therefore supports Interdependence Theory, demonstrating that partners have concordance of and mutual influence over one another's health behaviours (Lewis et al., 2002) and corresponds with recent literature on spousal influence on exercise behaviours in cancer survivors (Myers-Virtue et al., 2015). However, whilst this may translate into mutually beneficial behaviour change practices, concordance can also inhibit progress through the stages of PA behaviour change if both partners are, as found by Manne et al. (2012), directly or indirectly impacting on one another's behaviour in a negative way.

Therefore, although underpinning PA consultations with Interdependence Theory combined with the TTM shows promise with some couples, this may not necessarily result in an intervention that is applicable to all CRC-Ss and their partners and that will produce intended positive changes in selected outcomes.

SA also revealed the discursive construction of partner as caregiver, by partners themselves, to be an important feasibility concern. Partners were the main caregivers during treatment and recovery for CRC-Ss and the effects of this for some appeared to influence their engagement with and impact on the consultation. Partners could sometimes overwhelm and infantilise the CRC-S and dominate the consultation, resulting in the CRC-Ss disengaging from the process. This issue appeared to be connected to partner anxiety and fear following the cancer experience. Partners had residual and continued fears concerning the CRC-Ss condition. This is supported by Sklenarova (2015) who found that caregivers have unmet support needs, primarily with regards to fear of the patients' condition. This finding is also supported by the findings of Mitchell et al. (2013) that the spouses of long-term cancer survivors are likely to suffer from anxiety. Compared to non-caregivers, caregivers are more likely to suffer psychological, behavioural and physiological effects of a cancer diagnosis (Bevans et al., 2012). This has important feasibility implications for including partners in a PA intervention. On the one hand,

partners of CRC-Ss could be motivated to take part in an intervention that could benefit the health of the CRC-S, as well as also being an important target population for which PA could ameliorate the personal after effects of their partners' cancer diagnosis. On the other hand, the effects of cancer experience on the partners could inhibit CRC-Ss during the consultation, if the partner is still living with mental and physical issues that prevent them from supporting PA behaviour change in the CRC-S. Consideration in the development of this study was given to the psychosocial impacts of a cancer diagnosis on a spouse or partner, but the role of the partner specifically as caregiver was not anticipated or accounted for in the decision to include them in the intervention. **Future research should investigate the role of partner as caregiver and the implications of this for joint PA consultations and other behaviour change interventions. Educating partners about the benefits and contraindications of PA (or other health behaviour) could help to overcome this problem**.

Another important feasibility consideration that arose from SA was the role and positioning of the researcher. As a young, female student, many participants became invested in me and my research; the rapport established with participants - which facilitated the consultations - was often built around their perception of me. This has important implications for intervention development and future research, as the presence of the student as researcher could have impacted on the success of recruitment, retention and compliance, as well as outcome results. This was a PhD research study; all participants were aware of this and many became invested on a personal level that may not otherwise exist in a larger trial. Therefore extrapolating from the feasibility results of this study to future trial development must be done with caution.

Closely linked to both the elements of the partner and the researcher, was the triadic nature of the consultation, which arose as a key element. The researcher as interventionist was working closely with the couple to go through the consultation process and bring about behaviour change. The PA consultation therefore, rather than being dyadic, was triadic in nature. Although the target population was a dyad, when an interventionist is

introduced it becomes a triad. Throughout the consultations, there were varying, supportive interactions between the CRC-Ss, the partners and the interventionist which highlighted the feasibility of introducing an additional person into the PA consultation**. Future research should take account of and focus on the interaction of the triad within the consultation and build in specific triadic support strategies** (McCollum et al., 1994).

SA also highlighted that, for some participants, the PA consultation represented a therapeutic opportunity, during which to discuss, primarily, health concerns and share personal experience. These participants were less engaged in the consultation process. Therapeutic opportunity in research was first discussed by Birch (2000) and is usually contextualised within qualitative interview research that investigates sensitive or private aspects of people's lives (Birch 2000). However, analysis of this study demonstrates that trial and intervention processes can have therapeutic effects on participants in research, representing, as discussed by Haynes (2006), a therapeutic journey. This is a little considered area of intervention research and is important for establishing feasibility. Participants' motivation for taking part in the research and the experience and journey they go through whilst taking part needs to be considered as these could impact on recruitment, retention, compliance and outcome.

It is important to note that the SA found elements of consultation structure, language and dialogue interwoven throughout the intervention between participating actors to underpin the consultation. These elements represent the interactive and conversational mechanisms through which couples engaged with the intervention; through which couples were supportive of one another or otherwise; through which they were interdependent or otherwise; through which they constructed their PA narratives; through which rapport was established with one another and the interventionist and through which they navigated the consultation, independently or as a couple. These elements fed in to others on the map as they demonstrated *how* participants engaged with one another, the interventionist and the consultation. It was not an objective of this study to assess the mechanisms through which the intervention might work; however, they are important to note, as the success

of behavioural interventions such as PA consultations is rooted in interpersonal dialogue and rapport and can make the difference between 100% attrition and no attrition. The interaction is integral to the success or failure of the consultation and the subsequent outcomes. Also, the quality of the interaction could have little effect on PA outcome but huge effect on whether or not participants persevere with the trial. This evidence can contribute beyond the trial itself, by contributing knowledge as to how psychosocial-based PA interventions work, ie. the possible social mechanisms through which they work. This is an area for future research. For the purposes of this study, SA of the consultation tapes helped to contextualise and make sense of the study outcomes gathered statistically and contribute to the analysis of whether or not the intervention is feasible.

As well as addressing the feasibility objectives, the SA shed further light on the barriers to PA faced by CRC-Ss and their partners. As well as many of the barriers that have also been found in literature on barriers to PA for CRC-Ss, such as lack of time and motivational barriers (Lynch et al., 2016; Fisher et al. 2016), additional barriers were detected throughout the consultation process that may not have immediately been thought of as barriers by participants, such as space and temporal elements for example. These barriers did not necessarily arise from the discussion of barriers to PA during the consultation with participants. Rather, through broader discussion and consultation processes, these barriers came to light and were able to be established through the method of SA on the consultation tapes. This further highlights the important contribution that SA can make to feasibility research. SA is a qualitative approach that assesses an entire situation and the elements that are key to and impacting on that situation. These are elements that have not necessarily been anticipated or purposefully investigated by means of evidence review and qualitative research strategies such as structured interviewing. SA permits the researcher to understand elements impacting on a whole situation and outcomes, including ones that may not otherwise have been considered. **Future situational analysis should build on the Ordered Situational Map presented in this study and use it as a platform for further research into joint PA consultations and other**

behavioural interventions. The results of the SA are important for the development of this intervention, as it has captured influences and instrumental features of the consultation that may lead to or hinder success in improving PA behaviour amongst CRC-Ss.

8.3: *Objective 3: To evaluate indicative effectiveness of the intervention on key outcome domains*

Objective measurement of PA using accelerometers found CRC-Ss in the intervention group to have the highest recorded total activity count per day of all groups, at all three time points. No increase in PA over time, as represented by total activity count per day, was recorded for any group except CRC-Ss in the control arm. For example, PA levels decreased over time from baseline to T1 and T2 by 5.5% and 2.4% respectively, from baseline, for CRC-Ss in the intervention group. Comparatively, CRC-Ss in the control group increased total activity count by 6.1% between baseline and T2. However, the control group recorded a 40.1% decrease over time in levels of moderate intensity activity, whereas the intervention group recorded a 20.1% increase. This suggests that although total activity decreased for CRC-Ss in the intervention group, when they were physically active they were spending more time at the recommended moderate level of PA following the intervention. This corresponds to research that found increased moderate intensity PA levels amongst CRC-Ss 12 months following a post-treatment PA intervention (Moug et al., 2017; Hawkes et al., 2013) and short term improvements in PA in CRC-Ss following PA interventions (Cramer et al., 2014). Despite the increase, the average time spent in moderate intensity activity for CRC-Ss in the intervention group was still 30 minutes short of the guidelines at T2. Had the study gone on longer than 6 months, in line with Hawkes et al. (2013), it is possible that the increase would have continued. The overall low levels of moderate intensity activity and high levels of sedentary behaviour of the CRC-Ss recorded by the accelerometers is consistent with objective monitoring of PA and sedentary time amongst CRC-Ss (Lynch et al., 2016).

Partners in both groups also recorded decreases in total activity counts over time; this decrease was nominal for partners in the intervention group but considerably higher for partners in the control group, at 21% and 14.5% decrease respectively from baseline. Again, partners in the intervention group increased time spent in moderate intensity activity by 22.2% from baseline to T1 following the intervention, bringing them within 10 minutes of the recommended PA guidelines. This is promising; however their PA levels then regressed between T1 and T2, to an average of 80.9 minutes of moderate intensity activity – 26.1% less than at baseline. This regression to the mean - which is common statistical phenomenon in RCTs of behavioural interventions (Barnett et al., 2004) – could be explained by a temporary change in PA levels as a result of being part of the study and the intervention, which then return to pre-intervention levels.

CRC-Ss and partners in the control group recorded the highest levels of moderate intensity activity at baseline and at subsequent time points. At each time point, with the exception of CRC-Ss at T2, CRC-Ss and partners in the control group were exceeding the PA guidelines. This suggests that the control group entered the study with existing high levels of PA, which could introduce bias into the data.

Inter-group difference in PA and low levels of increased moderate intensity PA could be explained by accelerometer cut points. Freedson cut points for adults were used (see Chapter Seven), which have been shown to have good agreement and correlation with PA levels in CRC-Ss (Boyle et al., 2015; Lynch et al., 2016; Vallance et al., 2014). However, these cut points are not age-specific and there was great variation in age between working age and retired age participants in the trial. Santos-Lozano et al. (2013) recommend that age-specific equations for cut points should be used to ensure the correct use and validity of data from accelerometers; therefore, this could explain variation in the results and **future studies should consider different thresholds for different intensities of PA in this population, or use cut points for older adults.**

Large standard deviation in objective PA outcome data is consistent with the findings regarding social support, concordance and interdependence

amongst couples (as discussed above). Results could be explained by varying levels of support, support for PA and concordance amongst couples. Interestingly, in self-reported support for PA, CRC-Ss in the intervention group – who increased levels of moderate intensity activity over time (see above) – also reported increased relationship support for PA from baseline to T1 and T2. Further, CRC-Ss in the intervention group also reported a 7.9% increase in GSE overtime. This suggests that joint PA consultations can increase support for PA behaviour change and GSE in CRC-Ss. Control group results support this assertion, as, although the control group reported higher relationship support at all three time points, they had higher and more concordant levels of moderate intensity PA than the intervention group to start with and at each time point (see below). This suggests they were already physically active and concordantly so.

Variation in results however, could also be explained by the small sample size and so interpretation should be carried out with caution.

Self-reported PA data (IPAQ) found PA levels to be considerably higher than those recorded objectively by the accelerometers. Based on the self-report data, the majority of participants in both intervention and control groups were classified as being in the moderate or high category for PA. Of the valid datasets, 54.5% of CRC-S in the intervention group were classified in the moderate category of PA and 18.2% in the high PA category. This was a consistent pattern over time; at T2, 54.5 % again were in the moderate category and 45.5% were in the high category. Similar results were recorded for partners in the intervention group. These results contradict the objective PA measures; however, over-reporting is a known problem in self-reported PA measures that affects reliability (Prince et al., 2008). Boyle et al. (2015) found considerable exposure to misclassification of PA amongst CRC-Ss in studies using self-report measures of moderate to vigorous PA, comparatively to those using accelerometer-based assessments. There was poor agreement and correlation between accelerometers self-reported PA (Boyle et al., 2015). This appears to be the case in the current study and, as such, measures of objective PA are considered representative of PA levels amongst participants during the trial.

Interestingly, self-reported and objectively monitored PA levels amongst participants in the control group were more closely aligned than those in the intervention group. As discussed, PA levels amongst CRC-Ss and partners in the control group were higher at baseline and subsequent time points than their counterparts in the intervention group; further, PA levels on average exceeded the PA guidelines in this group. Therefore the control group appear to have already been physically active. Evidence suggests therefore, that PA may not necessarily be subject to over-reporting in self-report outcome measures if participants are already sufficiently active. Implications are that it is those participants who are not partaking in sufficient levels of PA that are more likely to exaggerate their PA behaviour when self-reporting. CRC-Ss and partners in the control group also reported higher stages of change than the intervention group; again, this is consistent with PA outcome results.

Objective PA results demonstrate that CRC-Ss and partners recorded relatively similar total activity counts per day across all time points (mean = ≥76.6% concordance; maximum 96.6% concordance [control group at baseline]). There were also broadly similar recordings of minutes spent in different PA intensities for CRC-Ss and partners in both groups. This corresponds to literature that found correspondence of PA and other health behaviours in couples (Stimpton et al., 2006; Meyler et al., 2007). Specifically, between baseline and T1, CRC-Ss and partners in the intervention group recorded a 17.6% and 22.1% increase respectively in minutes spent in moderate intensity activity. At T2, there was only a very small increase for CRC-Ss (4 minutes) and a regression for partners. This indicates that PA consultations may produce short-term increases in moderate intensity PA for CRC-Ss and their partners and supports the inclusion of a partner in PA interventions for CRC-Ss. However, as previously discussed, partners may not necessarily be the best source of social support in PA consultations purely due to sharing health behaviours with one another.

No mild or severe anxiety or depression scores were recorded at baseline or follow-up. Variation in anxiety scores for CRC-S and partners in the control group however, suggest that some participants are experiencing

mild anxiety, despite higher recordings of moderate intensity PA. This is contrary to Vallance et al. (2015), who found PA to be positively associated with reduced anxiety in CRC-Ss.

Only nominal change was detected in depression subscale scores. This is consistent with Speck et al. (2010), who found little impact of PA on depression in cancer survivors and contrary to Craft et al. (2012) who reported PA to be positively associated with reduced depression in cancer survivors.

As previously discussed, most attrition in outcome data occurred for measures of anxiety and depression (HADS). Therefore, results must be interpreted with this in mind; it is possible that attrition in this outcome is due to non-compliance by those who are likely to score higher on scales of anxiety and depression and do not wish to complete the instrument.

CRC-Ss in both intervention arms reported high QOL at all time points. This is consistent with previous research which suggests CRC-Ss have high QOL (Tang et al., 2016; Jansen et al., 2010). Research suggests that PA can positively impact on QOL in CRC-Ss and therefore the high moderate intensity PA levels objectively and self-reported for CRC-Ss in the control group could explain high their high levels of QOL. Partners similarly reported high QOL in both groups.

FCR was not found to be a notable concern for CRC-Ss in either arm of the study. FCR results were low and consistent over the duration of the trial. Importantly however, FCR appeared to be more of an issue for the partners of CRC-Ss than the survivors themselves. This is a valuable finding for future intervention development, which should consider cancer fear and anxiety about recurrence and other comorbidities of the partners of people who have had a diagnosis of cancer. Partners appear to be worried about cancer recurrence in the survivor.

Based on this study, a PA intervention that is underpinned by the TTM would seem to be feasible and acceptable to CRC-Ss and their partners. The assumption made by the TTM is that an intervention is aimed at one person; PA consultations have until now been based on the idea of working with a lone individual. This approach fails to consider – beyond the incorporation of a brief social support element - the interdependence of people and their

support links with, for example, their partners or spouses. This intervention combined two key frameworks in order to make them fit for practical interventions with more than one person. The results show that joint PA consultation is a promising area of intervention with CRC-S. Partners are a potential source of social support for PA for CRC-Ss and appear willing to take part in an intervention study. However, despite the consultations addressing the PA behaviour of the couple, the partner was mainly positioned in a supportive role during consultations – as that of enabler to PA behaviour change in the CRC-Ss. This was not apparent in every consultation however, as discordance within couples and partner-specific concerns, such as fear for the health of the survivor, could result in the partner hindering progress in the consultation and therefore not having a supportive influence on behaviour change.

8.4: *Study Limitations*

In addition to those highlighted throughout the discussion, this study was subject to the following limitations:

- The external validity and generalisability of the results is limited, due to the small sample size of the study and the demographic characteristics of the sample population. Participants were predominantly white, well-educated and with high household income. There is evidence to suggest that those who are more highly educated are more likely to participate in clinical trials (Moorcroft et al., 2016). Extrapolation of findings to the broader CRC-S population must therefore be done cautiously. Further, recruitment was carried out at only one site, again making it difficult to infer from the findings. However, the success of recruitment from only one site provides very promising evidence of feasibility for a larger study.
- Attrition in key outcome data limits the strength of the findings of indicative effectiveness of these results. However, evidence of attrition in the data itself is an important feasibility finding of the study.

- Not including a PA log book along with accelerometers was a limitation of the study. Using a combination of accelerometer and PA diary gives a more accurate indication of an individual's habitual PA. I felt that including the log book would be a burden on participants given the other measures in the study and how much was already being asked of them. This information however, could be very valuable to the development of this intervention and should be included in future research. This would permit increased understanding of the feasibility of objective measures of PA with CRC-Ss and increase understanding of the PA behaviours of CRC-Ss.
- This study is unable to determine indicative effectiveness of PA consultations on long-term outcomes amongst participants.

Outcomes omitted from analysis:

Body composition: Body composition (ie. Fat and lean mass) was estimated using a portable foot-to-foot bioelectrical impedance monitor (Tanita TBF300 MA Body Composition Analyser, Harlow Printing Ltd, Tyne and Wear). There is good agreement between bio impedance and criterion methods for estimating fat mass and changes in body composition during weight loss in adults (Heyward et al., 1996). Unfortunately, due to my own researcher errors, I lost all data for this outcome, having collected it successfully over almost a year's course of data collection.

Chapter Ten: Conclusion

This final chapter will summarise the main conclusions of my study and the contribution it has made to the existing evidence base. I will then go on to recommend areas for future research.

There are an estimated 20,428 CRC-Ss in Scotland. Patients who go on to become long-term survivors of CRC are at risk of CRC recurrence, developing further cancers and of suffering from numerous co-morbidities and the ongoing effects of cancer treatment (Denlinger et al., 2011). PA is a non-pharmacological means of reducing these risks and improving the PA levels and health outcomes of CRC-Ss. Despite this, PA levels amongst CRC-Ss are low; more than half of CRC-Ss are not meeting the recommended PA guidelines (Aminisani et al., 2016). Further, there have been relatively few PA intervention studies and RCTs that have sought to address this and increase PA amongst CRC-Ss. To date, there have been no couple-based PA interventions with CRC-Ss. Partners are a potential source of social support for PA for CRC-Ss who could also benefit from a PA intervention. Therefore, this study aimed to address this gap in the literature by investigating the feasibility and indicative effectiveness of an RCT of a joint PA intervention with CRC-Ss and their partners.

This pilot study has contributed preliminary evidence of the potential of a PA intervention based on the TTM (PA consultations) with CRC-Ss and that incorporating social support mechanisms into the intervention may improve outcome. CRC-Ss were able to be successfully recruited and retained to an RCT of joint PA consultations. The published evidence base has expanded since I began my study, to include work carried out in this research area. I have come to similar conclusions in this study as those that have been carried out in tandem, with respect to the feasibility of recruiting, randomising and retaining CRC-Ss to studies of behaviour change interventions. This study was successful in also recruiting the partners of CRC-Ss to an RCT. This is the first couple-based PA intervention study with CRC-Ss and their partners. Involving partners in the intervention was feasible; they were willing and able to take part and engaged with the intervention. The partner primarily took on

a supportive, or enabling, role during PA consultations, rather than themselves becoming a focus of the intervention. The presence of a partner, although facilitative of engagement by CRC-Ss in some instances, had the opposite effect in others. The impact of the partner on the consultation appears to be connected to the concordance and interdependence of individual couples, in terms of personal relationship and PA beliefs. Partners may not always be the best source of social support for PA for CRC-Ss, although the incorporation of a social support mechanism into the intervention is feasible and highly recommended.

Indicative effectiveness of PA consultations on objectively measured PA levels amongst CRC-Ss and their partners showed a slight, short-term increase in levels of moderate intensity activity. Indicative effectiveness on other health outcomes, such as mental well-being, QOL and GSE was nominal.

This study applied theory to practice, by synthesising two theoretical models and applying them to a behavioural intervention. The TTM is an individual-level mode that has never been applied in a dyadic setting. By incorporating the Interdependence Model, I have demonstrated how these models can be applied together in practice. I have also provided a contribution to the methodological literature on feasibility studies. I have demonstrated the utility of SA in feasibility research and provided an Ordered Situational Map of joint PA consultations with CRC-Ss and their partners as a platform from which to build future research. To my knowledge, this is the first feasibility study to include SA.

10.1: *Recommendations for future research*

Based on the areas for future research highlighted in bold in Chapter 9 and inclusive of additional recommendations, suggested areas for future research includes:

1. A rigorous approach to PA intervention development with CRC-Ss, beginning with a systematic review and meta-analysis of feasibility research in this area.
2. From a systematic review and meta-analysis, progression criteria for an RCT could be developed.
3. Consider involving another family member or friend in the consultations.
4. Build up to inclusion of multiple sources of social support.
5. Carry out feasibility research with different interventionists.
6. Future research can build on the Situational Map and use it as a platform to investigate and refine joint PA consultations. Future research could look further into the SA and the relationships between key themes on the map. This could be extended to assessing individual and/or couple outcomes alongside a situational analysis of the consultations.
7. If this translates into a pilot, results of any SA can inform the refinement of quantitative data assessment tools, for example, fear of death amongst partners and perceived competency of the researcher or interventionist.
8. The mediating effects of relationship on PA and other outcomes should be investigated. This would require a larger sample size and validated relationship instrument.
9. Need systematic review and development of feasibility progression criteria
10. Future research may wish to investigate factors associated with attrition in data in PA intervention studies with CRC-Ss and strategies to overcome these.
11. Modifications to the questionnaire booklet need to be made to make it less burdensome and more relevant to participants. Also, barriers to completion of self-report measures of mental well-being and PA need to be investigated.

Based on the results of this study, I would recommend that further feasibility work be undertaken. There is space in the literature for a systematic review and meta-analysis of feasibility studies of PA interventions with CRC-Ss. This would be a good starting point from which to develop feasibility progression criteria for pilot studies. Avery et al. (2017) recommend that pre-specified progression criteria be applied to pilot studies and should include recruitment rates, intervention adherence, results of primary outcome data, degree of missing data within key outcomes and percentage of participants with missing data, as well as being fully reported using the extended CONSORT guidelines. My study has addressed these components and the results of this and other feasibility studies could be combined to produce pre-specified criteria for a comprehensive pilot study. Amber et al. (2017) discuss a traffic light system for pilot studies; based on this system and the current study, I would recommend amber, which denotes feasible with amendments. This study has provided enough evidence to suggest that a trial of PA consultations with CRC-Ss and their partners may be feasible. However, modification to study protocol and the intervention and further feasibility assessment is required. This study has demonstrated that this is a promising intervention. It is important to consider however, that this was a PhD study when assessing feasibility. Introducing one student researcher, who is carrying out an intervention as part of their education, adds a confounding factor that must be considered.

Further SA would permit a critical appreciation of the nature of the dyadic interaction and social support that takes place during PA consultations that are carried out jointly with CRC-Ss and their partners. This study has highlighted some of the mechanisms through which joint PA consultations might produce increased PA levels as the primary outcome (see Figure 9), but further, more in-depth research is needed.

Future research can build on the Situational Map and use it as a platform to investigate and refine joint PA consultations. Future research could look further into the SA and the relationships between key themes on the map. This could be extended to assessing individual and/or couple outcomes alongside a SA of the consultations. SA can provide qualitative assessment

that goes beyond the thematic; it can assess contextual factors and mechanisms in PA consultations and other behavioural interventions. As this study has demonstrated, SA highlights key elements for feasibility assessment that may not otherwise have been considered and this should be carried forward to future research.

Future feasibility research should also investigate the inclusion of other sources of social support in the intervention, such as other family members or friends. Van Putten et al. (2016) found not having a partner to be negatively correlated with PA. 76.7% of otherwise eligible CRC-Ss were excluded from this study as they did not have a partner. This means that CRC-Ss who could potentially benefit most from PA consultations were not included.

All of the recommendations above are part of the process of extending the evidence base for the development of a definitive RCT of joint PA interventions with CRC-Ss.

10.2: *Concluding remarks*

This study provides a small but important contribution to making evidence based medicine more robust. If methodology is weak at this early stage, it calls into question the validity of results at latter stages of research. This has important implications for evidence-based medicine that could be overcome by more extensive feasibility work early on in the intervention and methodological development stages. In a time of reduced funding, perhaps funding bodies should be insisting on feasibility studies as a precursor to Phase III and IV RCTs, with their results feeding into larger studies. This could potentially save time, money and build a more robust and rigorous evidence base, as well as improved outcomes. There are many examples of trials that are carried out without sufficient evidence of success that produce underpowered and questionable results (Pinto et al., 2013, Halpern et al., 2002). We need to rethink our approach to feasibility studies and the stages in which we generate our evidence. Evidence matters. Positive publication bias leads to pressure to jump steps in the research process – such as feasibility work. This then leads to potentially ethically questionable,

underdeveloped studies with spurious results. This ultimately undermines the integrity of evidence-based interventions.

Feasibility studies should be carried out before a pilot trial, where – as was the case with my study – there is insufficient evidence to support a pilot trial and more information is needed regarding the population, recruitment, intervention development etc. Feasibility studies should be conducted in an area of promise, where the right intervention could potentially have a significant impact on the population it is targeting and where an intervention is needed. The role of a feasibility study is to provide the foundations upon which to build and implement an intervention with maximum effect and least burden. Feasibility studies should be carried out to prevent waste of time and resources, to uphold the highest ethical standards and to ensure as far as possible robust intervention studies that produce relevant and valid research data that will contribute to the evidence base and ultimately inform policy and practice.

Since I began this study in 2009, there have been important developments for feasibility research, including an academic journal, *Pilot and Feasibility Studies* and new CONSORT guidelines developed specifically for the reporting of feasibility and pilot research (see Appendices). This highlights encouraging growth and progress for this area of research and represents a step forward in overcoming publication bias in published academic research. Feasibility work permits an area of promising research to be interrogated and assessed prior to embarking on a full RCT, which may be underpowered or under-evidenced as to feasibility of protocol and intervention as well as potential outcome. This study has demonstrated the importance of feasibility studies and added a contribution to PA intervention research with CRC-Ss.

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Appendix A

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	1
Authors *	Contact details for the corresponding author	n/a
Trial design	Description of pilot trial design (eg, parallel, cluster)	14-15
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	15-17
Interventions	Interventions intended for each group	19-20
Objective	Specific objectives of the pilot trial	11-13
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	21-25
Randomization	How participants were allocated to interventions	18
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	18
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	25-27
Recruitment	Trial status†	n/a
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	27
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	28-32
Harms	Important adverse events or side effects	33
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	34-39
Trial registration	Registration number for pilot trial and name of trial register	40
Funding	Source of funding for pilot trial	41

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future , definitive RCT.*

†Forconferenceabstracts.

Appendix B

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported in
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Chapters 2-6
	2b	Specific objectives or research questions for pilot trial	Chapter 4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Chapter 7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Chapter 7
Participants	4a	Eligibility criteria for participants	Chapter 7
	4b	Settings and locations where the data were collected	Chapter 7

	4c	How participants were identified and consented	Chapter 7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Chapter 7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Chapter 7
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Chapter 7
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	Chapter 7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Chapter 7
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	Chapter 7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Chapter 7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Chapter 7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Chapter 7
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Chapter 7
Results			
Chapteer 8	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Chapter 8

	13b	For each group, losses and exclusions after randomisation, together with reasons	Chapter 8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Chapter 8
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Chapter 8
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Chapter 8
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Chapter 8
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Chapter 8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Chapter 9
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Chapter 9
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Chapter 9
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Chapter 9
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Abstract
Protocol	24	Where the pilot trial protocol can be accessed, if available	Abstract
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Abstract
	26	Ethical approval or approval by research review committee, confirmed with reference number	Appendices

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

Appendix C

CRC-S example

EVALUATION FORM

Please complete the following questions by circling the answer that best applies to you, or give written answers where asked. Please complete the form as fully as possible – the information you provide will help to assess the study and will help the development of future studies.

1. Recruitment and group allocation

	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
a. I was happy with the way I was recruited to the study	1	2	3	4	5
b. I was fully informed about what taking part in the study would involve before I agreed to take part	1	2	3	4	5
c. I fully understood that I would be randomly assigned to either Group 1 (physical activity consultations) or Group 2 (no physical activity consultations)	1	2	3	4	5
d. I was satisfied with the way I was allocated to the group I was in	1	2	3	4	5
e. I was happy with the group I was in	1	2	3	4	5

2. Accelerometers, scales and questionnaires

	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
a. The questionnaires were easy to complete	1	2	3	4	5
b. The questionnaires were time consuming	1	2	3	4	5
c. Standing on the weighing scale was inconvenient	1	2	3	4	5
d. The accelerometer was comfortable to wear	1	2	3	4	5
e. The accelerometer interfered with my daily tasks	1	2	3	4	5

f. I wore the monitor at all times during the times I was asked to wear it	**Yes / No** **If you answered no, for what reason(s) did you not wear the monitor?**

3. <u>Satisfaction with the consultations</u>

	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
a. The consultations provided me with enough support to increase my level of physical activity	1	2	3	4	5
b. The consultations were delivered well	1	2	3	4	5
c. The consultation was helpful	1	2	3	4	5
d. I liked having the consultation with my partner	1	2	3	4	5
e. I enjoyed the consultations	1	2	3	4	5
f. The number of consultations was:	**not enough / just right / too many**				

4. <u>During the study</u>

	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
a. I worked hard to try to acheive the goals set out during the consultations	1	2	3	4	5
b. I used the goal sheets from the consultations to motivate me	1	2	3	4	5
c. My partner and I supported one another to be more physically active	1	2	3	4	5
d. I noticed positive changes in my physical health	1	2	3	4	5
e. I noticed positive changes in my mental well-being	1	2	3	4	5
f. I made changes to other aspects of my lifestyle (for example, diet)	**Yes / No** **If you answered yes, what did you change?**				

5. <u>Overall satisfaction</u>

	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
a. I feel satisfied with the study	1	2	3	4	5
b. My involvement in the study was enjoyable	1	2	3	4	5
c. Arranging home-visits with the researcher was convenient for me	1	2	3	4	5
c. The amount of contact with/from the researcher was too frequent	1	2	3	4	5
d. I would prefer to be part of a study on my own, without my partner	1	2	3	4	5
e. I would prefer to be part of a study with another relative or friend	1	2	3	4	5
f. I would prefer to be part of a study that takes place outwith my own home	1	2	3	4	5

6. <u>Since the study</u>

My involvement in the study has encouraged me to:		
a. Be more physically active	**Yes**	**No**
b. Set myself activity goals	**Yes**	**No**
c. Join a fitness centre, classes or walking club	**Yes**	**No**
d. Be more physically active with my partner	**Yes**	**No**
e. Discuss physical activity with my partner	**Yes**	**No**
Since taking part in the study my physical activity has:	**decreased / stayed the same / increased**	

Please use the space below if you wish to elaborate on any of the answers you have given above:

Please describe anything you particularly liked or disliked about the study, and any ways in which you feel the study could be improved:

Study likes	
Study dislikes	
Ways to improve the study	

Please use this space to provide any other comments

Thank you very much. Please post the evaluation forms back in the stamp-addressed envelope provided.

Appendix D: Evaluation sheet comments

	Study likes	Study dislikes	Ways to improve the study	Additional comments
CRC-S				
Intervention	'conduct of study excellent'	...	...	'I am not sure how helpful exercise consultations would really be if faced with problems of bad prognosis, employment, finance or relationships'
	'I liked the consultations, which I felt were carried out in a very friendly and informal manner. Encouraging and motivating to take more physical exercise'	…	…	…
	'I enjoyed learning about exercise levels. I enjoyed thinking that my involvement might be of general help in recovery from cancer.'	…	…	'I was not a good candidate for the study other than as an example of a middle-aged Scotsman who has little interest in exercise'
	'Home visits were good'	…	…	…
	'Was pleased with Pamela's encouragement to help me along.'	…	…	…
Control	'convenience of home visits; feeling of being part of a group study that would help others; reinforcement of our belief that exercise and diet can benefit our health; giving us hope for the future'	…	…	…

	'Easy to do' 'I liked the researcher's approach and sensitivity to the study.'	…	'I think what would be helpful is some information on the aftermath of cancer and the symptoms you have to learn to live with… Even some kind of dietary and nutrition would be helpful.'	'Prior to illness I was already a golf club member and member of fitness club… I don't know if it was the study or my self-esteem that encouraged me to get back to some physical activities.'
	…	…	'Some questions – I believe from existing proformas – could be improved.'	…
	…	…	…	'Sometimes I was asked the same question more than once in different categories.'
	'The idea that helping to improve people's lifestyle after cancer is worthwhile to them and therefore the population in general.'	…	…	…
	'Pamela is a very likeable, intelligent young lady and so enthusiastic. It was a pleasure to meet her and we wanted to help. We are interested in this study.'	'Silly questionnaires where the options given did not reflect what we wanted to say. Endless repetition of very similar questions. Badly worded! [Accelerometer] Belts slipped down or too tight around tummy (my cancer scar). Not comfortable.'	'Not have an elastic belt around abdomen; have more intelligently worded questionnaires and more freedom of reply.'	'The questionnaire options didn't reflect what we thought – a general criticism of mult-choice questionnaires.' 'Sorry to sound so negative, but we were in the ono-active control group!'
	'Very pleasant researcher.'	'Some of the questions were ambiguous and some answers were therefore contradictory.'	…	…

	'Any research in preventative medicine has great value. I liked the fact that my partner was involved too. Fairly straightforward. I like to be included in the outcomes.'	…	'Slightly simplify the questionnaire in parts; would like the study to be extended to food awareness'	…
	Study likes	**Study dislikes**	**Ways to improve the study**	**Additional comments**
Partner Intervention	'The friendly yet professional way in which the interviews etc. were conducted.'	'Maybe a bit more feedback during the study/trial wouldn't have gone amiss'	'More feedback'	'As a result of the study/consultations, I have taken part in two 10k and one 5k walks. I would never have done this prior to my involvement in the study. I'm looking forward to participating in more walks next year.'
	'motivation from the researcher and encouragement towards goals'	…	'I might have been better motivated if I'd known what the accelerometer recorded – did I reach my goals?'	'I enjoyed being involved in this study. All credit to the researcher; it is no easy task to go in to people's homes and motivate them in this way. My PA has gone back down but I still aspire to using the goals I was given!'
	…	…	…	'Very motivated, pleasant researcher who was comfortable working in home environment.'
	'Meeting Pamela was nice. Taking up swimming again was very pleasant'	'I disliked the accelerometer; found it uncomfortable to wear	…	…

		either under or over clothes. Did persist though'		
Control	…	'I did feel many of the questions were the same or very similar'	…	'I am already very active, playing golf and going to the gym.'
	'I liked the fact that taking part in the study may produce positive advice about exercise in regard to bowel cancer and that I contributed to that'	…	…	'We were already walking one hour daily and had an excellent diet'
	'Anything that may help people after or while dealing with cancer is worthwhile and I was happy to be involved in this study'	…	…	'I was already active before taking part in the study
	…	'Questionnaires need to be more carefully worded or explicit'	'Cut out extraneous sheets of questions – some seem to have been imported (uncritically) from other (American?) sources'	'The worksheets need to be thoroughly re-vamped because completing them – with so much not applicable to me – was often rather boring! Also, lack of opportunity to say 'maybe' rather than 'yes' or 'no'.'
	'I liked the manner in which the study was presented and the efficient way it was carried out'	…	…	…

Appendix E: Every day and long term goal sheets

What, When and Where

LONG TERM GOALS

1 month	3 months	6 months

Appendix F

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 2
West of Scotland Research Ethics Service
Western Infirmary
Ground floor, Tennent Building
38 Church Street
Glasgow
G11 6NT

Tel: 0141-211-6270
Fax: 0141-211-1847

15 August 2011

Miss Pamela Flynn
Cancer Care Research Centre
Department of Nursing and Midwifery
Unit 1 Scion House,
Stirling
FK9 4NF

Dear Miss Flynn

Study title:	**A pilot study of a randomised controlled trial to evaluate the effects of physical activity consultations on the physical activity levels and other health outcomes of people living with colorectal cancer and their partners**
REC reference:	**10/S0709/39**

This study was given a favourable ethical opinion by the Committee on 29 July 2010.

Research Ethics Committees are required to keep a favourable opinion under review in the light of progress reports and any developments in the study. You should submit a progress report for the study 12 months after the date on which the favourable opinion was given, and then annually thereafter. Our records indicate that a progress report is overdue. It would be appreciated if you could complete and submit the report by no later than one month from the date of this letter.

Guidance on progress reports and a copy of the standard NRES progress report form is available from the National Research Ethics Service website.

The NRES website also provides guidance on declaring the end of the study.

Failure to submit progress reports may lead to the REC reviewing its opinion on the study.

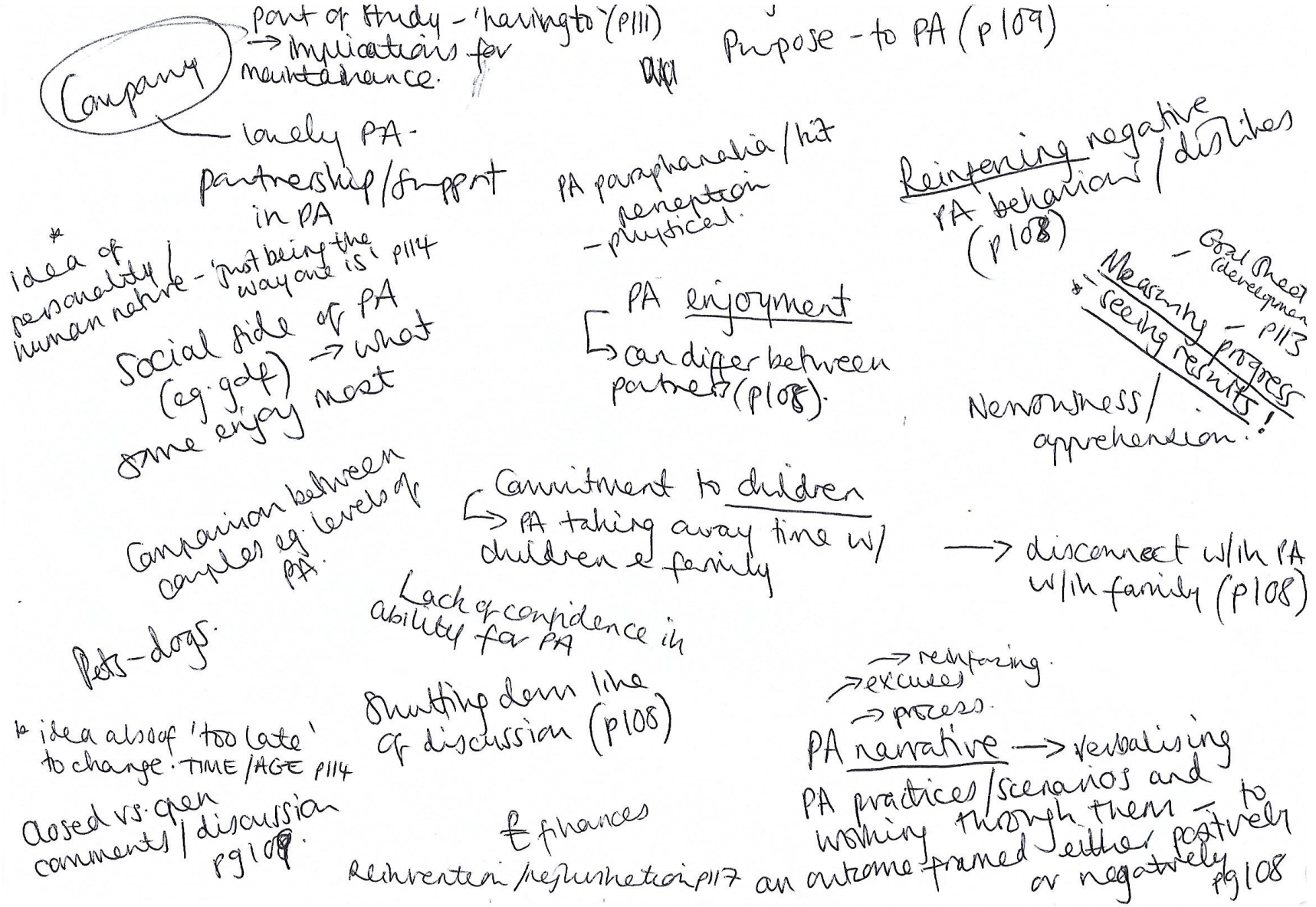
10/S0709/39:	**Please quote this number on all correspondence**

Yours sincerely

Sharon Jenner

Miss Sharon Jenner
Assistant Co-ordinator
E-mail: sharon.jenner@ggc.scot.nhs.uk

Delivering better health
www.nhsggc.org.uk


Company
part of study - 'having to' (P111)
→ implications for maintenance.
Purpose - to PA (P109)
solely PA - partnership/support in PA
PA paraphernalia / kit reception - physical.
Reinforcing negative PA behaviour / dislikes (P108)
idea of personality / human nature - 'just being the way one is' P114
Social side of PA (eg. golf) → what one enjoy most
PA enjoyment
↳ can differ between partner (P108).
Goal Sheet (development P113
Measuring progress / seeing results!
Nervousness / apprehension.
Comparison between couples eg. levels of PA.
↳ Commitment to children
↳ PA taking away time w/ children & family
→ disconnect w/in PA w/in family (P108)
Pets - dogs.
Lack of confidence in ability for PA
Shutting down line of discussion (P108)
→ reinforcing.
→ excuses
→ process.
PA narrative → verbalising PA practices/scenarios and working through them - to an outcome framed either positively or negatively pg108
idea also of 'too late' to change. TIME/AGE P114
closed vs. open comments / discussion pg108.
£ finances
Reinvention/Reformation P117


* Blame - for lack of PA? 35
Worry - post diag./treat.
→ partner & CRCS p135
! - diagnosis affects
Embarrassment - about PA together. p120.
* Realistic goals - important.
Benefits / incentives of PA
- weight loss
- fitter
Explaining oneself to researcher.
Post-op - 'stagnation' lingering feelings of diagnosis/treatment p131
Residual pain
Enjoyment - Lack of
Trying to stimulate this pg120
physical ability
Talking as one.
Researcher addressing participants ~~as~~ individually vs. as a couple.
In essence, 2 vs. 1 consultations.
③ Researcher as 'boss' pg. 127
↳ perception as instructor/in control, rather than participant.
Partner ceremony - CRC-S. p131
↓
Unsupportive of goals
↓
why? p132-133
Shifted vs. flowing consultation.
working w/ vs. against researcher/each other

Researcher motivating participants to ask questions of themselves - aim to, in effect, have participants guide ~~the~~ / navigate the consultation.

Sense of achievement/ failure

Roles of ~~participants~~ actors in consultation.

⇒ participants as active vs. inactive.

Sense of one partner being threatened by other's goals - trying to dismiss them. p92

Encouraging/discouraging. p92

Intentions - vs. reality p973.

PA

'Lies'

↳ deceit + deception → to researcher ↳ not wanting to lie. p994

Family-members

Friends

Commitments as potential support

Other health behaviours
- smoking
- diet

P67
- Working together
- problem-solving

For some, the idea of encouraging one another/PA together is novel.

Encouragement for PA begins during the consultation.

'Infantilising' of patient → patient as child. Partner as care-taker.

Partner setting realistic goals for process Change

Partner + researcher working together p.73-74

Marital 'roles'
Gender roles - p 92

-anxiety
Everyday troubles / racing mind.

Sense of how seriously taking goals. Partner often more invested. p994

→ Rapport between couples.

Researcher dominating consultation vs. participants dominating consultation

Participant as teacher/partner as teacher.

Researcher talking at participants.

Mutual reluctance to encouraging barrier → encouraging DEFENSIVE

Time

Conceding { Researcher = outsider; Dyad/Triad

Physical env. = countryside = city

Momentum

Habit (awareness q)
- Home
- flat
- house
- garden ??

spaces - work, urban, green space

Solutions / goals coming from participants → teasing out.

Partner resistance + CRC-S motivated

Work

Active living

Relationship between partners over time → this is v. important & sense of what used to be

Other people → other people's perceptions of doing PA
- neighbours

Researcher as source of knowledge / info.

Reasons for being more active
- motivations

Conversation - supporting/reinforcing what one another says.

Role of researcher
- PA guide
- student
- researcher

Public/friendly/neighbours invasion

Referring partner.

Surgery (fear)

Mirroring

Mood
- affecting PA

PROCESS

Excuses - partner reinforcing vs. overcoming

Saying what think re'er wants to hear -- humping cans along.

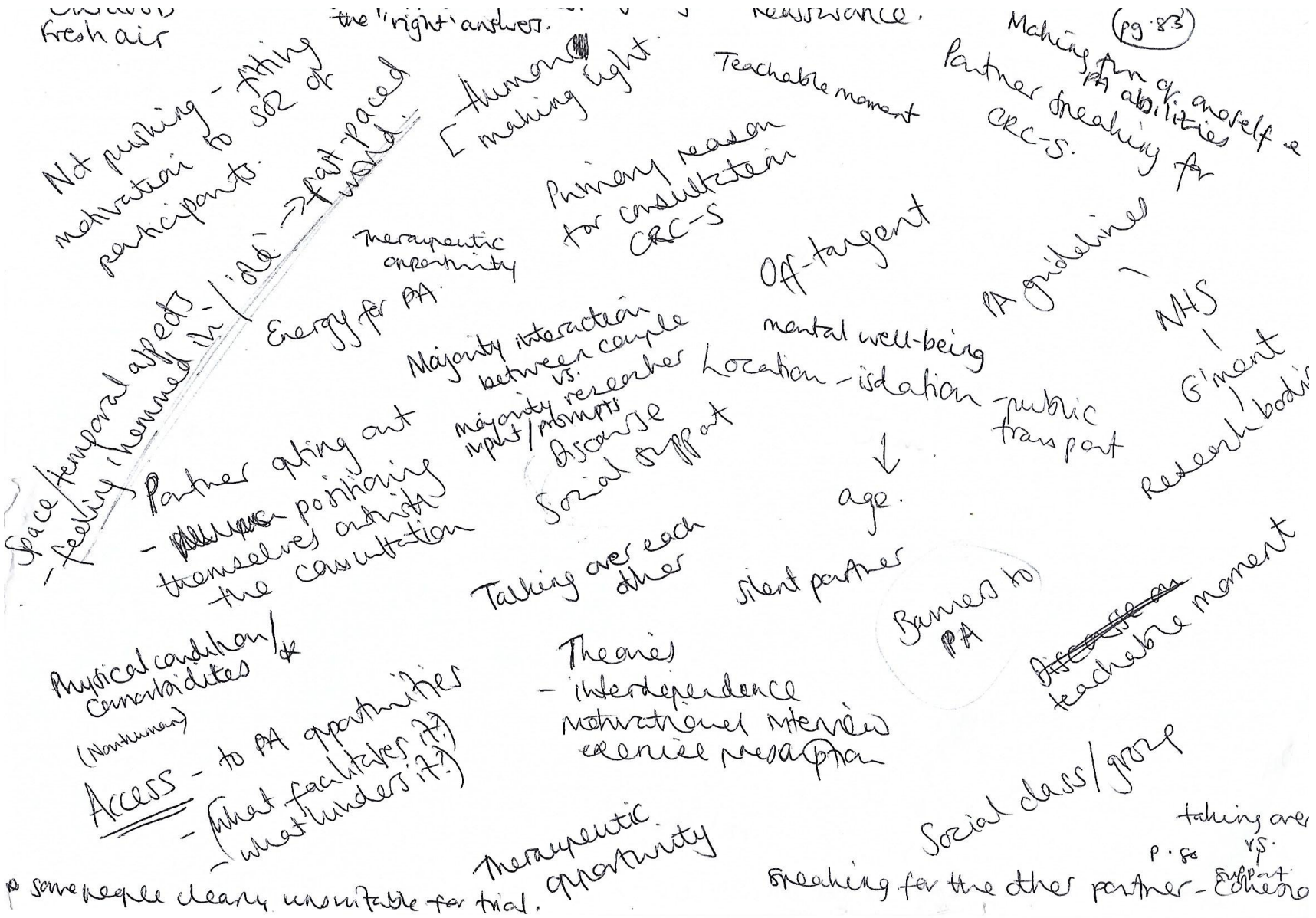
Depression

Researcher q's & prompts → participants open or v. closed (ie. one word or short responses).

Goal sheet.

Marital issues - closeness interconnectedness. intimacy pg. 55

& Most/all couples been married for a very long time.


fresh air
the 'right' answer.
relevance.
Making (pg. 83)
Not pushing - thing motivation to SOZ or participants.
Teachable moment
Partner speaking for CRC-S.
Space/temporal aspects - feeling rushed in 'doc' -> fast-paced world.
Primary reason for consultation CRC-S
therapeutic opportunity
Energy for PA.
Off-target
PA Guidelines
Majority interaction between couple vs. majority researcher input/prompts
mental well-being
Location - isolation - public transport
NHS / Grant / research bodies
Partner opting out - themselves positioning the consultation
Discourse
Social support
age.
Talking over each other
silent partner
Barriers to PA
Physical condition/ Contraindications
(Non-human)
Theories - interdependence motivational interview exercise prescription
Access - to PA opportunities - (what facilitates it) - what hinders it?)
Therapeutic opportunity
Social class/group
Speaking for the other partner - Explicit
taking over P. & vs.
* some people clearly unsuitable for trial.

Irritation - with partner pgfs ('that's what I said!')

→ Researcher as mediator. 'That's what Pam was saying...' Tension w/in couple → relationship tensions playing out in consultation -- affecting outcome / dynamic? Area for future research.

Time-management. → not wanting to be late.

Security in taking, esp; the car.

Engaged vs. wary. ~~Not~~ linked to me/research.

Car.

Public transport

[Religion - church - external influences, commitments. Walking to church.

Doctors - medical pgfs. ⇒ fear of attending vs. comfort → sought & found

Concept of mental & spiritual health & PA.

Vicious circle / cycle.

Cancer diagnosis ⇒ still on mind. A very present factor?

Processing during consultation -- times participants to engage w/ their PA behaviours. Think it through, play it out, work it through. Problem-solving

Risk perception → underestimate or inactivity vs. activity

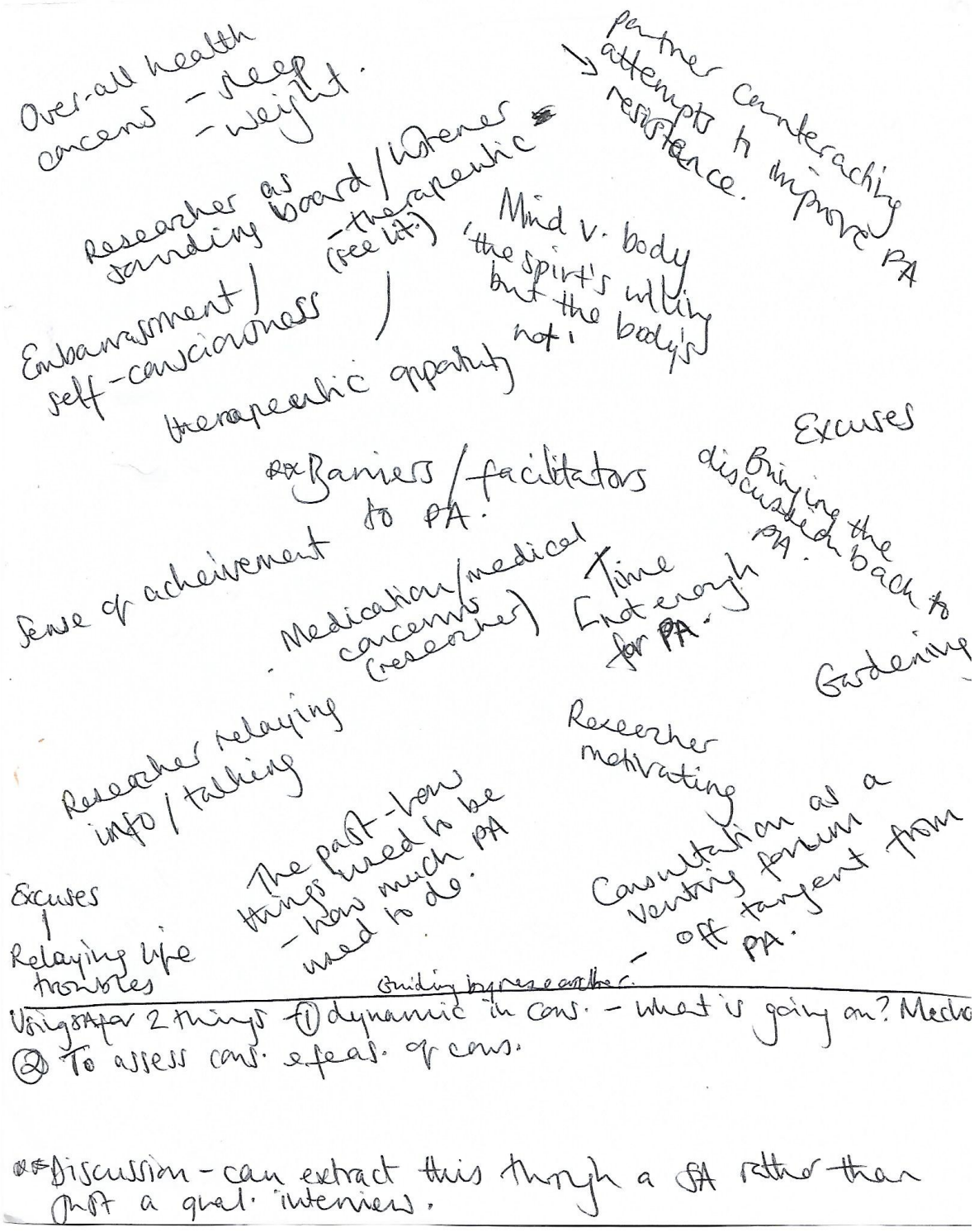
Some afraid to do PA for fear of exacerbating co-morbidities; others concerned w/ risks on not being physically active

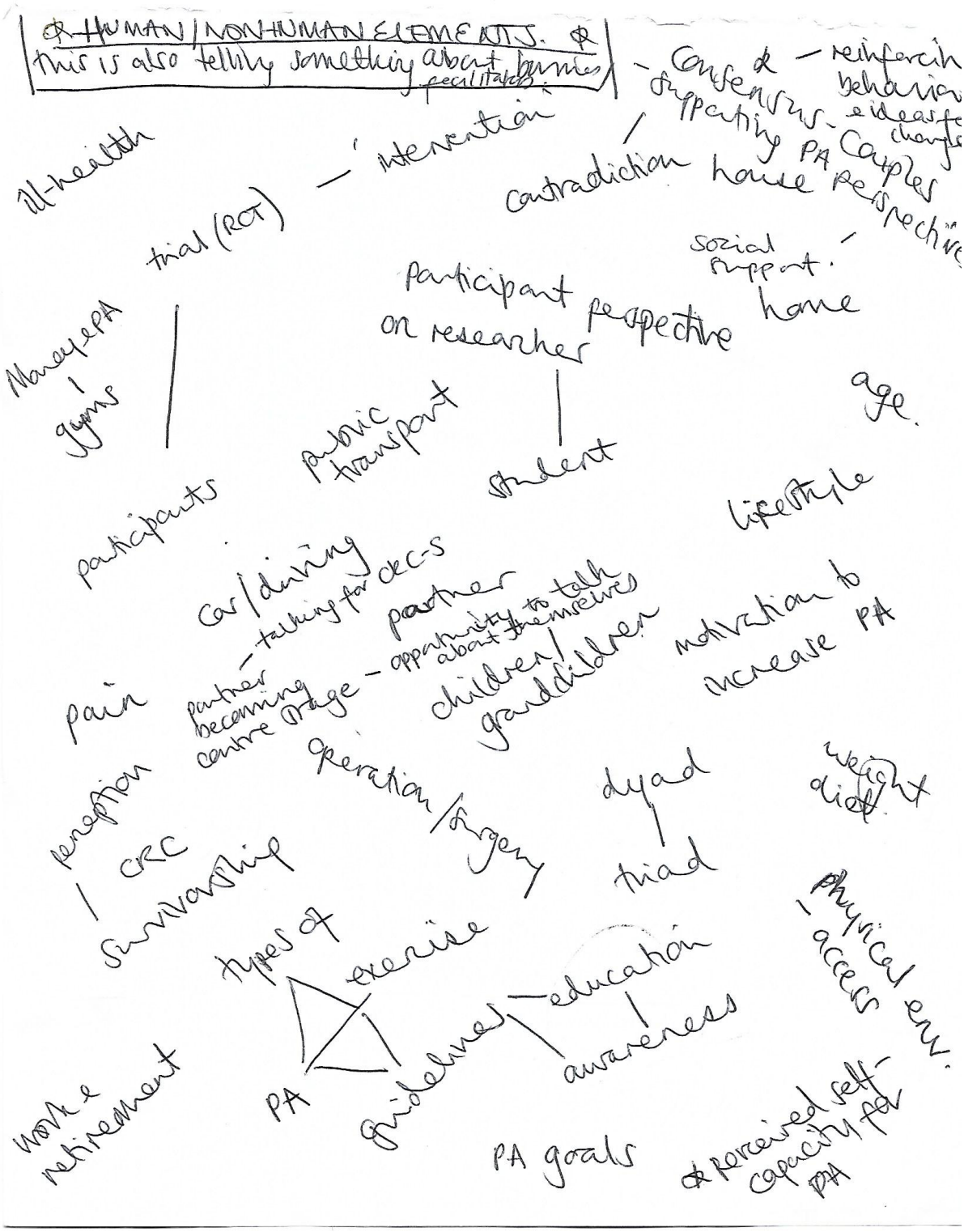
→ fear - of death. Ill-health.

fear of what docs may tell them


Reminiscing
reluctance / resistance
- support
Awareness - of PA guidelines. perception that PA moving is enough.
Engaged? - sometimes
Keeping each other right.
SOC
Health professionals
Process - the consultation - change in relationship/ interaction between couple.
health benefits
researcher embarrassing
Story-telling → associated w/ support / age / disinhibition
age
['can't do' due to age
dyad - triad
Communication
[sentence forming, eg.
weather
'Laziness' - being perceived as lazy.
perception of what constitutes PA.
- associated w/ age.
transition through uni. → lack of exp. → ambitious goals
PA perception - tiredness
Therapeutic spatiality
VS.
formal consultation
[Partner concerns
partner therapeutic app. (where cohesion was afterwards received).
'We'll' need to try - support / interdependence
'You'll' / 'you can' - support / encouragement
2 positions of partner
LANGUAGE!
Developing a bond / connection w/ researcher - bringing them into the fold.
interrupting
Competition between workers


Age differ. between partic. researcher-researcher. of researcher. Speaking for the other partner
setting goals together / apart
for the other partner.
Warming
- w/ partner & w/ researcher
→ goal sheets facilitate this.
Dialogue - between partners/ partner & researcher.
→ sometimes minimal intervention by researcher. Partner work together through it (researcher)
Repetition
Depending the other partner.
Engaging w/ goal that → wants it to be realistic
Warming w/ researcher
[supporting / agreeing
research study
v.
intervention
→ feeling of conv. belonging to researcher, not participan
Going out
- activity v. PA.
(p. 43
Questions
- drawing conv. to motivate
Rapport.
Gender
Postraining - gender - age
Dependence on partner for PA.
Working together
- checking check.
Confidence
'We'
[dyad & triad.
PA message.
Detail
- relevant
- irrelevant
Goal sheets
[Goal sheets seem to work well
- FOCUS - means of bringing conv. back to topic.
Comorbidities
Time
TRANS.
Time across conversation
[participants 'often' - more open to discussion & setting goals
Change from lack of confidence → ambitious goals
TRANS.


Over-all health concerns - sleep - weight.
Researcher as sounding board / listener - therapeutic (see lit.)
Embarrassment / self-consciousness /
therapeutic opportunity
Mind v. body 'the spirit's willing but the body's not.
partner counteracting attempts to improve PA
resistance.
**Barriers / facilitators to PA.
Sense of achievement
Medication/medical concerns (researcher)
Time Not enough for PA.
Excuses
Bringing the discussion back to PA.
Gardening
Researcher relaying info / talking
Excuses
Relaying life troubles
The past - how things used to be - how much PA used to do.
Researcher motivating
Consultation as a venting forum - off tangent from PA.
Using SA for 2 things ① dynamic in cons. - what is going on? Mech
② To assess cons. efficacy of cons.
**Discussion - can extract this through a SA rather than just a qual. interview.


& HUMAN / NON-HUMAN ELEMENTS &
This is also telling something about barriers / facilitators
- Consensus & - reinforcin
supporting PA - Couples behavior
contradiction home perspectiv
ill-health
trial (RCT) - intervention
social support - home
Participant perspective
or researcher
Money+PA / gyms
participants
public transport
student
age
lifestyle
car/driving - taking for decs
partner
pain
partner becoming carer stage - opportunity to talk about themselves
children/ granddildren
motivation to increase PA
perception / CRC survivorship
operation/surgery
dyad
triad
weight diet
types of exercise
physical env. / access
education / awareness
guidelines
PA
work e retirement
PA goals
& perceived self-capacity for PA

Appendix H

Cancer Care Research Centre
School of Nursing, Midwifery and Health
Unit 1, Scion House
University of Stirling
Stirling, FK9 4NF,
Telephone: +44 (0)1786 849260
Facsimile: +44 (0)1786 460060
Scotland

A pilot study of a randomised controlled trial to evaluate the effects of physical activity consultations on the physical activity levels and other health outcomes of colorectal cancer survivors and their partners

PARTICIPANT INFORMATION LEAFLET

You are being invited to take part in a physical activity study. This study is being conducted in the Greater Glasgow and Clyde area.

Who am I?
My name is Pamela Flynn and I am a PhD student studying with the Cancer Care Research Centre at the University of Stirling. I have a background in Public Health Research and have previously worked on a number of health research projects. For my PhD, I am carrying out a research study with colorectal cancer survivors and their partners.

What is the purpose of this study?
I am conducting a study of a randomised controlled trial to test how effective physical activity consultations are at increasing physical activity and improving the health of people who have had a diagnosis of colorectal cancer and their partners. The findings will be used to advise the development of a larger scale randomised controlled trial.

I will be measuring the physical activity levels of people who have had a diagnosis of colorectal cancer and their partners three times over 6 months, using accelerometers and questionnaires. I will also measure mental well-being, quality of life and body fat. I will also be collecting information about perceptions of cancer, health beliefs and relationship support.

Why have you been contacted?
I am seeking your consent to take part in this study because you have completed surgery and treatment for colorectal cancer in the last 32 months, or you are the partner of someone who has completed surgery and treatment for colorectal cancer in the last 32 months.

Do you have to take part?
No. It is up to you if you want to take part. If you do, please keep this information sheet for your reference. You will be asked to sign a consent form to confirm that you wish to take part in the study. If you decide to take part, you are free to withdraw from the study at any time and without giving a reason. Your medical care will not be affected in any way whether or not you decide to take part in the study.

What will it involve if you agree to take part in the study?
If you take part in this study, you and your partner will be randomly assigned to either Group 1 or Group 2. You will have an exactly equal chance of being assigned to either group.

Couples in Group 1 will receive physical activity consultations. I will conduct 2 physical activity consultations with you and your partner over 6 months. These will take place in your home. The consultations will involve a 1-2 hour face-to-face discussions with you and your partner (together) and will include for example, assessment of your current levels of physical activity, discussion of your pros and cons of being active, exploration of physical activity options and setting realistic physical activity goals for you both. You will be asked to wear an accelerometer whilst you are awake, for 7 days, on three separate occasions over the 6 months. The accelerometer is a small monitor that is worn on a belt around the waist and which records the amount of time a person spends being physically active. The accelerometer will measure how active you are during the 7 days that you are wearing it. Your body fat will also be measured, using a scale. You will also be asked to complete a series of short questionnaires about your physical activity.

If you are assigned to Group 2, you will not receive physical activity consultations and will continue to receive usual care provided to you by your GP and hospital clinical team. You will be asked to wear an accelerometer for 7 days on three separate occasions over the 6 months. The accelerometer is a small monitor that is worn on a belt around the waist and which records the amount of time a person spends being physically active. The accelerometer will measure how active you are during the 7 days that you are wearing it. Your body fat will also be measured, using a scale. You will also be asked to complete a series of short questionnaires about your physical activity which will take no more than an hour to complete.

What are physical activity consultations?
Physical activity consultations involve face-to-face discussions with the researcher and include, for example, assessment of current levels of physical activity, discussions of pros and cons of being active, exploration of physical activity options and the setting of realistic physical activity goals. The aim of

the consultation is to develop an activity plan that is tailored to your lifestyle, motivation and health status. The activity plan will be developed for you as a couple, although the physical activities may vary and you may choose to exercise independently of one another.

Will you be paid for taking part in the study?
No.

Are there any risks involved if you take part in the study?
Physical activity consultations are client-centred and focus on your needs and abilities therefore there are no likely health-related risks to you as a result of increasing your physical activity. To minimise any potential health risks of participating in increased levels of physical activity however, if you suffer from unstable cardiac or respiratory disease, or any other concurrent medical conditions that prevent physical activity, you will be unable to take part in this study. If you have any health concerns about taking part in this study, please contact your GP.

What are the benefits of taking part in the study?
If you are allocated to Group 1 you may benefit from physical activity consultations as they may help to increase your levels of physical activity in the short and/or long-term which could potentially have numerous health benefits for you.

Will your taking part be kept confidential?
Yes. You will not be named in any reports that are written about the study. The results of the study will be reported without mentioning any names. All data, including your consent form and questionnaires, will be kept in a locked filing cabinet at the University of Stirling. Only the PhD student and research supervisors will have access. In ten years time all of these data will be destroyed.

What will happen if I no longer wish to take part in the study?
Taking part in the study is entirely voluntary. You are free to withdraw from the study at any time. Your medical care will not be affected in any way if you decide to withdraw from the study.

What will happen to the results of the study?
The results of this study will be written up and presented in a PhD thesis. The results will also be published in academic journals. A summary of the results will be posted to you at the end of the study.

Who is conducting this study?
Pamela Flynn (MA, MSc), PhD student (Cancer Care Research Centre, School of Nursing, Midwifery and Health, University of Stirling) is conducting this study with the support of supervisor Dr. Gill Hubbard PhD, MSc, BA (co-director, Cancer Care Research Centre, School of Nursing, Midwifery and Health, University of Stirling).

Has this study been reviewed by an ethics committee?
This study has been reviewed by an NHS Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans in accordance with the requirements of the Clinical Trials Regulations. In this case, the reviewing Committee was the West of Scotland Research Ethics Committee 2, which has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available to monitors from the University of Stirling and NHS Glasgow and Clyde whose role is to check that this research is properly conducted and the interests of those taking part are adequately protected.

What if I wish to complain about the study?
If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Stirling, who are acting as the research sponsor. Details are available from Gill Hubbard. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to Greater Glasgow and Clyde NHS Board, Dalian House, PO Box 15329, 350 St. Vincent Street, GLASGOW G3 8YZ. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against Glasgow and Clyde Health Board, but you may have to pay your legal costs.

Who do I contact for further information?
You can contact Pamela Flynn for further information about the study. If you would like further information or advice from someone who is not involved in the study please contact Dr. Liz Forbat.

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Thank you for taking the time to read this and to consider taking part in the study.

Appendix I

Physical activity consultation content

1) Assessing stage of change

Regular Physical Activity

- Accumulating at least 30 minutes of moderate intensity physical activity 5 days of the week.
- Participating in 3, 20 minute continuous sessions of vigorous exercise a week

☐ 1: Not thinking about doing more physical activity

☐ 2: Starting to think about doing more physical activity

☐ 3: Being physically active occasionally, but not regularly

☐ 4: Being regularly physically active for less than 6 months

☐ 5: Being regularly physically active for longer than 6 months

2) Explain what physical activity is and intensity level

Explain different forms of physical activity

- *Active living (Walking, taking the stairs)*
- *Exercise (Swimming, exercise class)*
- *Sport (Football, hockey)*

3) Why be more active?

Detail benefits of physical activity for individual

4) Decision balance

Go through pros & cons of increasing physical activity

Pros and cons of becoming more active

Your pro's of becoming more active	Your con's of becoming more active
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.

5) Overcoming barriers

Discuss ways of overcoming barriers to becoming more active

Your con's of becoming more active	Ways to overcome con's
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.

6) Current physical activity level

Evaluate current physical activity levels.

*Patient can be repeat this process in a few weeks to check progress

Seven day record of physical activity (or use SPAQ or diary)

Example	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Brisk walk to shops 20 minutes							
Digging in garden 10 minutes							

7) Go through current guidelines & discuss discrepancy between guidelines & individuals level of physical activity (How much more activity do they need to do to achieve the initial target of accumulating 30 minutes of moderate intensity physical activity on most days of the week?)

8) Identifying opportunities and setting goals
Can they think of ways to increase their activity?

Activities you might consider
1.
2.
3.
4.
5.
6.

Planning what to do and where and when it will take place. Make first week goals within reach from where they are now. Two to three days with new activities is a good way to start. Think of taking at least 4 weeks to build up to the 30 minutes on most days of the week target.

Day of Week	What When and Where	√ when you achieve
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Source of local activities.

Develop long term goals

1 month	3 months	6 months
1. Walk back from work (10 minutes) at least 3 days a week	Increase walking to accumulate at least 40 minutes a day, 5 times a week	Complete sponsored 4km walk
2.		
3.		
4.		
5.		

* Remember SMARTER

9) Finding support
What do they need help with? For example, need someone to:

- ☐ Be active with you
- Listen to your struggles or triumphs
- Remind you to be active
- Offer expertise or good advice (i.e. health professional, books, etc.)
- Motivate you to be active
- Help make it easier to be active (i.e. look after the children so you have time to go for a walk, etc.)
- Other _____

Name	What things would you like them to do to help?

10) Relapse prevention: Maintaining behaviour change

Triggers or risky situations that can cause a lapse in my physical activity	What can you do to prevent these lapses?
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.

Appendix J

Cancer Care Research Centre
Linking reality with science

UNIVERSITY OF STIRLING
SCHOOL OF NURSING, MIDWIFERY AND HEALTH

Home-based physical activity consultations with colorectal cancer survivors and their partners

Questionnaire for colorectal cancer survivors

Second Questionnaire date **Version 2.2** **Issue**

First Questionnaire

S for Patient Study identifier

P for Partner

(S/P)	**N**	**N**	**N**	**N**	**N**	**N**	**N**

N = digits for number code

For study office use only

Date Received	Entered in D/base

SECTION 1: Personal Details

By answering the questions below, we will be able to describe participants who were involved in the study.

1. From the following list, what best describes your current situation?

☐	Self-employed	☐	Looking after family-home
☐	In paid employment (full or part-time)	☐	Full-time student
☐	Unemployed	☐	Long term sick or disabled
☐	Retired from paid work	☐	On a government training scheme
☐	On maternity leave	☐	Something else (please give details)

_____

2. Including income provided by you, your spouse/partner and others you regard as family who <u>live in the same household</u>, what was your total household income (from all sources, <u>*not just your income but other members of your family*</u>) before taxes in the last calendar year? (Your answers are confidential however, if you do not wish to answer this question please move on to section 2).)

☐	Under £9999	☐	£20000 – £24999	☐	£35000 - £39000
☐	£10000 – 14999	☐	£25000 - £29999	☐	£40000 - £49000
☐	£15000 – 19999	☐	£30000 - £34999	☐	£50000 and above

3. Are you currently being treated for any of the following medical conditions?

☐	Depression	☐	Hip fracture

	Anxiety
	Other psychological problems
	Neurological disease
	Dementia
	Migraine
	Kidney disease
	Liver disease
	Back pain
	Obesity and/or body mass index >30
	Stroke/TIA (Transient Ischaemic Attack)
	Other cerebrovascular disease
	Hypertension
	Angina
	Ischaemic heart disease
	Heart attack/ Myocardial infarction (MI)
	Congestive heart failure
	Peripheral vascular disease
	Other vascular disease
	Diabetes
	Crohn's disease
	Ulcerative colitis
	Ulcer disease
	Rheumatoid arthritis
	Arthritis
	Osteoarthritis
	Osteoporosis
	Other connective tissue disease

	Hip fracture
	Upper gastrointestinal disease
	Inflammatory bowel disease
	Inflammatory bowel disease
	Upper gastrointestinal cancer
	Large bowel (colon and rectum) cancer
	Breast cancer
	Gynaecological cancer
	Prostate cancer
	Lung cancer
	Leukaemia
	Lymphoma
	Other cancer: _____
	Epilepsy
	Parkinson's disease
	Multiple sclerosis
	Motor neurone disease
	Renal disease
	Asthma or emphysema
	Chronic obstructive pulmonary disease
	Other respiratory disease
	AIDS HIV?
	Hemiplegia
	Anaemia
	Hearing impairment
	Visual impairment
	Any other health conditions? (please specify)

_____

Thank you. Please move on to section 2.

SECTION 2: General Self-efficacy

Please circle the answer that applies to you for each question.				
	Not at all true	**Hardly true**	**Moderately true**	**Exactly true**
I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
If someone opposes me, I can find the means and ways to get what I want.	1	2	3	4
It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
I am confident that I could deal efficiently with unexpected events.	1	2	3	4
Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
I can solve most problems if I invest the necessary effort.	1	2	3	4
I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
If I am in trouble, I can usually think of a solution.	1	2	3	4
I can usually handle whatever comes my way.	1	2	3	4

Thank you. Please move on to section 3.

SECTION 3: Quality of life

By answering the questions below, we will find out about your quality of life.

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

PHYSICAL WELL-BEING

		Not at all	A little bit	Somewhat	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

SOCIAL/FAMILY WELL-BEING

		Not at all	A little bit	Somewhat	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

EMOTIONAL WELL-BEING

		Not at all	A little bit	Somewhat	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

FUNCTIONAL WELL-BEING

		Not at all	A little bit	Somewhat	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

ADDITIONAL CONCERNS (FACT-F)

		Not at all	A little bit	Somewhat	Quite a bit	Very much
H17	I feel fatigued	0	1	2	3	4
H12	I feel weak all over	0	1	2	3	4
An1	I feel listless ("washed out")	0	1	2	3	4
An2	I feel tired	0	1	2	3	4
An3	I have trouble starting things because I am tired	0	1	2	3	4
An4	I have trouble finishing things because I am tired	0	1	2	3	4
An5	I have energy	0	1	2	3	4
An7	I am able to do my usual activities	0	1	2	3	4
An8	I need to sleep during the day	0	1	2	3	4
An12	I am too tired to eat	0	1	2	3	4
An14	I need help doing my usual activities	0	1	2	3	4
An15	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
An16	I have to limit my social activity because I am tired	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.

ADDITIONAL CONCERNS (FACT-C)

		Not at all	A little bit	Somewhat	Quite a bit	Very much
C1	I have swelling or cramps in my stomach area	0	1	2	3	4
C2	I am losing weight	0	1	2	3	4
C3	I have control of my bowels	0	1	2	3	4
C4	I can digest my food well	0	1	2	3	4
C5	I have diarrhea	0	1	2	3	4

	(diarrhoea)					
C6	I have a good appetite	0	1	2	3	4
C7	I like the appearance of my body	0	1	2	3	4
Q2	Do you have an ostomy appliance? (Mark one box) If yes, please answer the next two items:	**No**	**Yes**	-	-	-
C8	I am embarrassed by my ostomy appliance	0	1	2	3	4
C9	Caring for my ostomy appliance is difficult	0	1	2	3	4

Thank you. Please move on to section 4.

SECTION 4: Psychological well-being

By answering the questions below, we will find out about your psychological well-being.

Read each item and place a firm tick in the box opposite the reply that comes closest to how you have been feeling <u>in the past week</u>. Don't think too long about your answers – give an immediate response to each item.

Tick only one box ☒ in each section

1. I feel tense or wound up:

Most of the time ☐
A lot of the time ☐
Time to time ☐
Not at all ☐

2. I feel as if I am slowed down:

Nearly all the time ☐
Very often ☐
Sometimes ☐
Not at all ☐

3. I still enjoy the things I used to enjoy:

Definitely as much ☐
Not quite so much ☐
Only a little ☐
Hardly at all ☐

4. I get a sort of frightened feeling like butterflies in the stomach:

Not at all ☐
Occasionally ☐
Quite often ☐
Very often ☐

5. I get a sort of frightened feeling

6. I have lost interest in my

as if something awful is about to happen:

- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

appearance:

- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

7. I can laugh and see the funny side of things:

- As much as I always could ☐
- Not quite as much now ☐
- Definitely not so much now ☐
- Not at all ☐

8. I feel restless as if I have to be on the move:

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

9. Worrying thoughts go through my mind:

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

10. I look forward with enjoyment to things:

- As much as ever I did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

11. I feel cheerful:

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

12. I get sudden feelings of panic:

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

13. I can sit at ease and feel relaxed:

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme:

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Thank you. Please move on to section 5.

SECTION 5: Fear of cancer recurrence

This section of the questionnaire will ask about your fear of cancer recurrence. **By recurrence, we mean the possibility that the cancer could return or progress in the same place or in another part of the body.** Please read each statement and indicate to what degree it applied to you **DURING THE PAST MONTH** by circling the appropriate number.

0	**1**	**2**	**3**	**4**
Never	Rarely	Sometimes	Most of the time	All the time

The following situations make me think about the possibility of cancer recurrence:					
1. Television shows or newspaper articles about cancer or illness	0	1	2	3	4
2. An appointment with my doctor or other health professional	0	1	2	3	4
3. Medical examinations (e.g. annual check-up, blood tests, X-rays)	0	1	2	3	4
4. Conversations about cancer or illness in general	0	1	2	3	4
5. Seeing or hearing about someone who is ill	0	1	2	3	4
6. Going to a funeral or reading the obituary section of the paper	0	1	2	3	4
7. When I feel unwell physically or when I am sick	0	1	2	3	4
8. Generally, I avoid situations or things that make me think about the possibility of cancer recurrence	0	1	2	3	4

0	**1**	**2**	**3**	**4**
Not at all	A little	Somewhat	A lot	A great deal

9. I am worried or anxious about the possibility of cancer recurrence	0	1	2	3	4
10. I am afraid of cancer recurrence	0	1	2	3	4
11. I believe it is normal to be worried or anxious about the possibility of cancer recurrence	0	1	2	3	4
12. When I think about the possibility of cancer recurrence, this triggers other unpleasant thoughts or images (such as death, suffering, the consequences for my family)	0	1	2	3	4
13. I believe that I am cured and that the cancer will not come back	0	1	2	3	4

14. In your opinion, are you at risk of having a cancer recurrence?

0	**1**	**2**	**3**	**4**
Not at all at risk	A little at risk	Somewhat at risk	A lot at risk	A great deal at risk

15. How often do you think about the possibility of cancer recurrence?

0	**1**	**2**	**3**	**4**
Never	A few times a month	A few times a week	A few times a day	Several times a day

16. How much time <u>per day</u> do you spend thinking about the possibility of cancer recurrence?

0	**1**	**2**	**3**	**4**
I don't think about it	A few seconds	A few minutes	A few hours	Several hours

0	**1**	**2**	**3**	**4**
Not at all	A little	Somewhat	A lot	A great deal

When I think about the possibility of cancer recurrence, I feel:					
17. Worry, fear or anxiety	0	1	2	3	4
18. Sadness, discouragement or disappointment	0	1	2	3	4
19. Frustration, anger or outrage	0	1	2	3	4
20. Helplessness or resignation	0	1	2	3	4

My thoughts or fears about the possibility of cancer recurrence disrupt:					
21. My social or leisure activities (e.g. outings, sports, travel)	0	1	2	3	4
22. My work or everyday activities	0	1	2	3	4
23. My relationships with my partner, my family, or those close to me	0	1	2	3	4
24. My ability to make future plans or set life goals	0	1	2	3	4
25. My state of mind or my mood	0	1	2	3	4
26. My quality of life in general	0	1	2	3	4

0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal

27. I feel that I worry excessively about the possibility of cancer recurrence	0	1	2	3	4
28. Other people think that I worry excessively about the possibility of cancer recurrence	0	1	2	3	4
29. I think that I worry more about the possibility of cancer recurrence than other people who have been diagnosed with cancer	0	1	2	3	4

0 Never	1 Rarely	2 Sometimes	3 Most of the time	4 All the time

When I think about the possibility of cancer recurrence, I use the following strategies to reassure myself:					
30. I call my doctor or other health professional	0	1	2	3	4
31. I go to the hospital or clinic for an examination	0	1	2	3	4
32. I examine myself to see if I have any physical signs of cancer	0	1	2	3	4
33. I try to distract myself (e.g. do various activities, watch television, read, work)	0	1	2	3	4
34. I try not to think about it, to get the idea out of my mind	0	1	2	3	4
35. I pray, meditate or do relaxation	0	1	2	3	4
36. I try to convince myself that everything will be fine or I think positively	0	1	2	3	4
37. I talk to someone about it	0	1	2	3	4
38. I try to understand what is happening and deal with it	0	1	2	3	4
39. I try to find a solution	0	1	2	3	4
40. I try to replace this thought with a more pleasant one	0	1	2	3	4
41. I tell myself “stop it”	0	1	2	3	4
42. Do you feel reassured when you use these strategies?	0	1	2	3	4

Thank you. Please move on to Section 6.

Section 6: PROCESSES OF CHANGE QUESTIONNAIRE

The following experiences can affect the physical activity habits of some people. Think of similar experiences you may be currently having or have had **during the last month**. Then rate how frequently the event occurs. Please circle the number that best describes your answer for each experience. **How frequently does this occur?**

	Never	Occasionally		Repeatedly		Office use only
1. Instead of remaining inactive I engage in some physical activity	1	2	3	4	5	g
2. I tell myself I am able to keep exercising if I want to	1	2	3	4	5	b
3. I put things around my home to remind me of exercising	1	2	3	4	5	f
4. I tell myself that if I try hard enough I can keep exercising	1	2	3	4	5	b
5. I recall information people have personally given to me on the benefits of exercise	1	2	3	4	5	a
6. I make commitments to exercise	1	2	3	4	5	b
7. I reward myself when I exercise	1	2	3	4	5	j
8. I think about information from articles and advertisements on how to make exercise a regular part of my life	1	2	3	4	5	a
9. I keep things around my place of work that remind me to exercise	1	2	3	4	5	f
10. I find society changing in ways that make it easier for the exerciser	1	2	3	4	5	h
11. Warnings about health hazards of inactivity affect me emotionally	1	2	3	4	5	c
12. Dramatic portrayals of the evils of inactivity affect me emotionally	1	2	3	4	5	c
13. I react emotionally to warnings about an	1	2	3	4	5	c

inactive lifestyle						
14. I worry that inactivity can be harmful to my body	1	2	3	4	5	c
15. I am considering the idea that regular exercise would make me a healthier, happier person to be around	1	2	3	4	5	i
16. I have someone on whom I can depend when I am having problems with exercising	1	2	3	4	5	e

	Never	**Occasionally**		**Repeatedly**		**Office use only**
17. I read articles about exercise in an attempt to learn more about it	1	2	3	4	5	a
18. I try to set realistic exercise goals for myself rather than setting myself up for failure by expecting too much	1	2	3	4	5	j
19. I have a healthy friend that encourages me to exercise when I don't feel up to it	1	2	3	4	5	e
20. When I exercise, I tell myself that I am being good to myself by taking care of my body	1	2	3	4	5	j
21. Exercise is my special time to relax and recover from the days worries, not a task to get out of the way	1	2	3	4	5	g
22. I am aware of more and more people encouraging me to exercise these days	1	2	3	4	5	h
23. I do something nice for myself for making efforts to exercise more	1	2	3	4	5	j
24. I have someone who points out my rationalizations for not exercising	1	2	3	4	5	e
25. I have someone who provides feedback about	1	2	3	4	5	e

my exercising						
26. I remove things that contribute to my inactivity	1	2	3	4	5	f
27. I am the only one responsible for my health, and only I can decide whether or not I will exercise	1	2	3	4	5	b
28. I look for information related to exercise	1	2	3	4	5	a
29. I avoid spending long periods of time in environments that promote inactivity	1	2	3	4	5	f
30. I feel I would be a better role model for others if I exercised regularly	1	2	3	4	5	d
31. I think about the type of person I will be if I keep exercising	1	2	3	4	5	i

32. I notice that more businesses are encouraging their employees to exercise by offering fitness courses and time off to exercise	1	2	3	4	5	h
33. I wonder how my inactivity affects those people who are close to me	1	2	3	4	5	d
34. I realise that I might be able to influence others to be healthier if I would exercise	1	2	3	4	5	d
35. I get frustrated with myself when I don't exercise	1	2	3	4	5	i
36. I am aware that many health clubs now provide free crèches to their members	1	2	3	4	5	h
37. Some of my close friends might exercise more if I would	1	2	3	4	5	d
38. I consider that fact that I would feel more confident in myself if I exercised regularly	1	2	3	4	5	i
39. When I feel tired I make myself exercise anyway because I know I will feel better afterwards	1	2	3	4	5	g
40. When I am feeling tense, I find exercise a great way to relieve my worries	1	2	3	4	5	g

Decisional Balance

Please circle the response which shows to what extent you agree with the following statements.

	Strongly Disagree				Strongly Agree
1. I would be healthier if I was more physically active	1	2	3	4	5
2. I would feel better about myself if I was more physically active	1	2	3	4	5
3. Other people would respect me more if I was more physically active	1	2	3	4	5
4. My family and friends would get to spend less time with me if I was more physically active	1	2	3	4	5
5. I would feel that I was wasting my time if I was more physically active	1	2	3	4	5
6. I would probably be sore and uncomfortable if I was more physically active	1	2	3	4	5

Self Efficacy

Please circle a number on each of the following scales to indicate how confident you feel in your ability to continue to exercise regularly under the following situations.

I am confident I can participate in regular physical activity when:					
	Not at all confident				Very confident
1. I am tired	1	2	3	4	5
2. I am in a bad mood	1	2	3	4	5
3. I feel I don't have the time	1	2	3	4	5
4. I am on holiday	1	2	3	4	5
5. It is raining or snowing	1	2	3	4	5

Thank you. Please move on to Section 7.

SECTION 7: Relationship

By answering the questions below, we will find out about your relationship with your partner. **Please circle or mark one number per line to indicate your response as it applies to your relationship now.**

1	2	3	4
A lot	Somewhat	A little	Not at all

We would now like to ask you some questions about your relationship with your partner				
1. How much do they really understand the way you feel about things?	1	2	3	4
2. How much can you rely on them if you have a serious problem?	1	2	3	4
3. How much can you open up to them if you need to talk about your worries?	1	2	3	4
4. How much do they criticise you?	1	2	3	4
5. How much do they let you down when you are counting on them?	1	2	3	4
6. How much do they get on your nerves?	1	2	3	4

7. How close is your relationship with your spouse or partner?

Tick <u>one</u> box

Very close ☐

Quite close ☐

Not very close ☐

Not at all close ☐

1	2	3	4	5	6	7
Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly agree	Moderately agree	Strongly agree

In the last week I...							
8. ... have had someone to encourage me to participate in physical activity on a regular basis.	1	2	3	4	5	6	7
9. … I have had someone to participate with me in physical activity.	1	2	3	4	5	6	7
10. … I felt supported in having a regular pattern of physical activity.	1	2	3	4	5	6	7

Thank you. Please move on to Section 8.
SECTION 8: INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

☐ Yes

☐ No → ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include travelling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

_____ **days per week**

☐ No vigorous job-related physical activity → ***Skip to question 4***

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

_____ **days per week**

☐ No moderate job-related physical activity → ***Skip to question 6***

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

☐ No job-related walking → ***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day**
_____ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

☐ No travelling in a motor vehicle → ***Skip to question 10***

9. How much time did you usually spend on one of those days **travelling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day**
_____ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No bicycling from place to place → ***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**
_____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No walking from place to place → ***Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**
_____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

☐ No vigorous activity in garden or yard → ***Skip to question 16***

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

☐ No moderate activity in garden or yard → ***Skip to question 18***

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

☐ No moderate activity inside home → ***Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day**
_____ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

☐ No walking in leisure time → ***Skip to question 22***

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day**
_____ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

☐ No vigorous activity in leisure time → ***Skip to question 24***

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **days per week**

☐ No moderate activity in leisure time → ***Skip to PART 5: TIME SPENT SITTING***

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?
_____ **hours per day**
_____ **minutes per day**

PART 5: TIME SPENT SITTING

These questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ **hours per day**
_____ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ hours per day
_____ minutes per day

PART 6: PHYSICAL ACTIVITY SELF-EFFICACY SCALE

These questions will help us understand your confidence in your ability to change your level of physical activity. Please circle which answer applies to you for each question. If you are *very uncertain* circle 1, *rather uncertain* circle 2, *rather certain* circle 3, and *very certain* circle 4.				
	Very uncertain	**Rather uncertain**	**Rather certain**	**Very certain**
How certain are you that you could overcome the following barriers? I can imagine to carry out my exercise intentions, ...				
... even when I have worries and problems.	1	2	3	4
... even if I feel depressed.	1	2	3	4
... even when I feel tense.	1	2	3	4
... even when I'm tired.	1	2	3	4
... even when I am busy.	1	2	3	4

Thank you for completing this questionnaire. Please hand the questionnaire to Pamela Flynn when she next visits.

Cancer Care Research Centre
Linking reality with science

UNIVERSITY OF STIRLING

SCHOOL OF NURSING, MIDWIFERY AND HEALTH

Home-based physical activity consultations for colorectal cancer survivors and their partners

Questionnaire for partners of colorectal cancer survivors

Second Questionnaire date **Version 2.4** **Issue**

First Questionnaire

S for Patient Study identifier

P for Partner

(S/P)	N	N	N	N	N	N	N

N = digits for number code

For study office use only

Date Received	Entered in D/base

SECTION 1: Personal Details

By answering the questions below, we will be able to describe participants who were involved in the study.

1.. From the following list, what best describes your current situation?

☐	Self-employed	☐	Looking after family-home
☐	In paid employment (full or part-time)	☐	Full-time student
☐	Unemployed	☐	Long term sick or disabled
☐	Retired from paid work	☐	On a government training scheme
☐	On maternity leave	☐	Something else (please give details)

_____

2. Including income provided by you, your spouse/partner and others you regard as family who <u>live in the same household</u>, what was your total household income (from all sources, <u>*not just your income but other members of your family*</u>) before taxes in the last calendar year? (Your answers are confidential however, if you do not wish to answer this question please move on to section 2).)

☐	Under £9999	☐	£20000 – £24999	☐	£35000 - £39000
☐	£10000 – 14999	☐	£25000 - £29999	☐	£40000 - £49000
☐	£15000 – 19999	☐	£30000 - £34999	☐	£50000 and above

3. Are you currently being treated for any of the following medical conditions?

☐	Depression	☐	Hip fracture
☐	Anxiety	☐	Hip fracture
☐	Other psychological problems	☐	Upper gastrointestinal disease

☐	Neurological disease	☐	Inflammatory bowel disease
☐	Dementia	☐	Inflammatory bowel disease
☐	Migraine	☐	Upper gastrointestinal cancer
☐	Kidney disease	☐	Large bowel (colon and rectum) cancer
☐	Liver disease	☐	Breast cancer
☐	Back pain	☐	Gynaecological cancer
☐	Obesity and/or body mass index >30	☐	Prostate cancer
☐	Stroke/TIA (Transient Ischaemic Attack)	☐	Lung cancer
☐	Other cerebrovascular disease	☐	Leukaemia
☐	Hypertension	☐	Lymphoma
☐	Angina	☐	Other cancer: _____
☐	Ischaemic heart disease	☐	Epilepsy
☐	Heart attack/ Myocardial infarction (MI)	☐	Parkinson's disease
☐	Congestive heart failure	☐	Multiple sclerosis
☐	Peripheral vascular disease	☐	Motor neurone disease
☐	Other vascular disease	☐	Renal disease
☐	Diabetes	☐	Asthma or emphysema
☐	Crohn's disease	☐	Chronic obstructive pulmonary disease
☐	Ulcerative colitis	☐	Other respiratory disease
☐	Ulcer disease	☐	AIDS HIV?
☐	Rheumatoid arthritis	☐	Hemiplegia
☐	Arthritis	☐	Anaemia
☐	Osteoarthritis	☐	Hearing impairment
☐	Osteoporosis	☐	Visual impairment
☐	Other connective tissue disease	☐	Any other health conditions? (please specify)

_____

Thank you. Please move on to section 2.

SECTION 2: General Self-efficacy

Please circle the answer that applies to you for each question.				
	Not at all true	**Hardly true**	**Moderately true**	**Exactly true**
I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
If someone opposes me, I can find the means and ways to get what I want.	1	2	3	4
It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
I am confident that I could deal efficiently with unexpected events.	1	2	3	4
Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
I can solve most problems if I invest the necessary effort.	1	2	3	4
I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
If I am in trouble, I can usually think of a solution.	1	2	3	4
I can usually handle whatever comes my way.	1	2	3	4

Thank you. Please move on to section 3.

SECTION 3: Quality of life

The following questions ask how you feel about your quality of life, health, or other areas of your life. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.
Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Thank you. Please move on to Section 4.

SECTION 4: Psychological well-being

By answering the questions below, we will find out about your psychological well-being.

Read each item and place a firm tick in the box opposite the reply that comes closest to how you have been feeling <u>in the past week</u>. Don't think too long about your answers – give an immediate response to each item.

Tick only one box ☒ in each section

1. I feel tense or wound up:

Most of the time	☐
A lot of the time	☐
Time to time	☐
Not at all	☐

2. I feel as if I am slowed down:

Nearly all the time	☐
Very often	☐
Sometimes	☐
Not at all	☐

3. I still enjoy the things I used to enjoy:

Definitely as much	☐
Not quite so much	☐
Only a little	☐
Hardly at all	☐

4. I get a sort of frightened feeling like butterflies in the stomach:

Not at all	☐
Occasionally	☐
Quite often	☐
Very often	☐

5. I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly	☐
Yes, but not too badly	☐
A little, but it doesn't worry me	☐
Not at all	☐

6. I have lost interest in my appearance:

Definitely	☐
I don't take so much care as I should	☐
I may not take quite as much care	☐
I take just as much care as ever	☐

7. I can laugh and see the funny side of things:

As much as I always could	☐
Not quite as much now	☐
Definitely not so much now	☐
Not at all	☐

8. I feel restless as if I have to be on the move:

Very much indeed	☐
Quite a lot	☐
Not very much	☐
Not at all	☐

9. Worrying thoughts go through my mind:

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

10. I look forward with enjoyment to things:

- As much as ever I did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

11. I feel cheerful:

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

12. I get sudden feelings of panic:

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

13. I can sit at ease and feel relaxed:

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme:

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Thank you. Please move on to section 5.

SECTION 5: Cancer risk and cancer worry

By answering the questions below, we will find if you feel at risk of colorectal and other cancers and how much you worry about it. **Please circle or mark the number that most closely reflects your answers.**

-1 Much lower	**-2** Lower	**0** Neutral	**1** Higher	**2** Much higher

1. How has your partner's diagnosis affected your perceptions of your own chances of developing colorectal cancer? My chances of developing cancer are now...	-1	-2	0	1	2
2. Compared to people <u>with</u> a family history of colorectal cancer, what are your chances of developing colorectal cancer? My chances of developing colorectal cancer compared to people <u>with</u> a family history of colorectal cancer are....	-1	-2	0	1	2
3. Compared to people <u>without</u> a family history of colorectal cancer, what are your chances of developing colorectal cancer? My chances of developing colorectal cancer compared to people <u>without</u> a family history of colorectal cancer are....	-1	-2	0	1	2

4. How worried are you about developing colorectal cancer?

1 Not worried at all	**2** A bit worried	**3** Quite worried	**4** Very worried

Now answer the following two questions using this scale:

1 Not at all	**2** A little	**3** Somewhat	**4** A lot

5. How much does your worry affect your mood?	1	2	3	4
6. How much does your worry affect your ability to perform your daily activities?	1	2	3	4

7. How worried are you about developing other types of cancer?

1	**2**	**3**	**4**
Not worried at all	A bit worried	Quite worried	Very worried

Now answer the following two questions using this scale:

1	**2**	**3**	**4**
Not at all	A little	Somewhat	A lot

8. How much does your worry affect your mood?	1	2	3	4
9. How much does your worry affect your ability to perform your daily activities?	1	2	3	4

10. How much control do you feel you have over whether you develop colorectal cancer?

1	**2**	**3**	**4**
None at all	A bit	Moderate	A lot

Thank you. Please move on to Section 6.

Section 6: PROCESSES OF CHANGE QUESTIONNAIRE

The following experiences can affect the physical activity habits of some people. Think of similar experiences you may be currently having or have had **during the last month**. Then rate how frequently the event occurs. Please circle the number that best describes your answer for each experience. **How frequently does this occur?**

	Never	Occasionally		Repeatedly		Office use only
41. Instead of remaining inactive I engage in some physical activity	1	2	3	4	5	g
42. I tell myself I am able to keep exercising if I want to	1	2	3	4	5	b
43. I put things around my home to remind me of exercising	1	2	3	4	5	f
44. I tell myself that if I try hard enough I can keep exercising	1	2	3	4	5	b
45. I recall information people have personally given to me on the benefits of exercise	1	2	3	4	5	a
46. I make commitments to exercise	1	2	3	4	5	b
47. I reward myself when I exercise	1	2	3	4	5	j
48. I think about information from articles and advertisements on how to make exercise a regular part of my life	1	2	3	4	5	a
49. I keep things around my place of work that remind me to exercise	1	2	3	4	5	f
50. I find society changing in ways that make it easier for the exerciser	1	2	3	4	5	h
51. Warnings about health hazards of inactivity affect	1	2	3	4	5	c

me emotionally						
52. Dramatic portrayals of the evils of inactivity affect me emotionally	1	2	3	4	5	c
53. I react emotionally to warnings about an inactive lifestyle	1	2	3	4	5	c
54. I worry that inactivity can be harmful to my body	1	2	3	4	5	c
55. I am considering the idea that regular exercise would make me a healthier, happier person to be around	1	2	3	4	5	i
56. I have someone on whom I can depend when I am having problems with exercising	1	2	3	4	5	e
	Never	**Occasionally**		**Repeatedly**		**Office use only**
57. I read articles about exercise in an attempt to learn more about it	1	2	3	4	5	a
58. I try to set realistic exercise goals for myself rather than setting myself up for failure by expecting too much	1	2	3	4	5	j
59. I have a healthy friend that encourages me to exercise when I don't feel up to it	1	2	3	4	5	e
60. When I exercise, I tell myself that I am being good to myself by taking care of my body	1	2	3	4	5	j
61. Exercise is my special time to relax and recover from the days worries, not a task to get out of the way	1	2	3	4	5	g
62. I am aware of more and more people encouraging me to exercise these days	1	2	3	4	5	h
63. I do something nice for myself for making efforts to exercise more	1	2	3	4	5	j
64. I have someone who	1	2	3	4	5	e

points out my rationalizations for not exercising						
65. I have someone who provides feedback about my exercising	1	2	3	4	5	e
66. I remove things that contribute to my inactivity	1	2	3	4	5	f
67. I am the only one responsible for my health, and only I can decide whether or not I will exercise	1	2	3	4	5	b
68. I look for information related to exercise	1	2	3	4	5	a
69. I avoid spending long periods of time in environments that promote inactivity	1	2	3	4	5	f
70. I feel I would be a better role model for others if I exercised regularly	1	2	3	4	5	d
71. I think about the type of person I will be if I keep exercising	1	2	3	4	5	i

72. I notice that more businesses are encouraging their employees to exercise by offering fitness courses and time off to exercise	1	2	3	4	5	h
73. I wonder how my inactivity affects those people who are close to me	1	2	3	4	5	d
74. I realise that I might be able to influence others to be healthier if I would exercise	1	2	3	4	5	d
75. I get frustrated with myself when I don't exercise	1	2	3	4	5	i
76. I am aware that many health clubs now provide free crèches to their members	1	2	3	4	5	h
77. Some of my close friends might exercise more if I would	1	2	3	4	5	d
78. I consider that fact that I would feel more confident in	1	2	3	4	5	i

myself if I exercised regularly						
79. When I feel tired I make myself exercise anyway because I know I will feel better afterwards	1	2	3	4	5	g
80. When I am feeling tense, I find exercise a great way to relieve my worries	1	2	3	4	5	g

Decisional Balance

Please circle the response which shows to what extent you agree with the following statements.

	Strongly Disagree				Strongly Agree
7. I would be healthier if I was more physically active	1	2	3	4	5
8. I would feel better about myself if I was more physically active	1	2	3	4	5
9. Other people would respect me more if I was more physically active	1	2	3	4	5
10. My family and friends would get to spend less time with me if I was more physically active	1	2	3	4	5
11. I would feel that I was wasting my time if I was more physically active	1	2	3	4	5
12. I would probably be sore and uncomfortable if I was more physically active	1	2	3	4	5

Self Efficacy

Please circle a number on each of the following scales to indicate how confident you feel in your ability to continue to exercise regularly under the following situations.

I am confident I can participate in regular physical activity when:					
	Not at all confident				Very confident
6. I am tired	1	2	3	4	5
7. I am in a bad mood	1	2	3	4	5
8. I feel I don't have the time	1	2	3	4	5
9. I am on holiday	1	2	3	4	5
10. It is raining or snowing	1	2	3	4	5

Thank you. Please move on to Section 7.

SECTION 7: Relationship

By answering the questions below, we will find out about your relationship with your partner. **Please circle or mark one number per line to indicate your response as it applies to your relationship now**

1	2	3	4
A lot	Somewhat	A little	Not at all

We would now like to ask you some questions about your relationship with your partner				
1. How much do they really understand the way you feel about things?	1	2	3	4
2. How much can you rely on them if you have a serious problem?	1	2	3	4
3. How much can you open up to them if you need to talk about your worries?	1	2	3	4
4. How much do they criticise you?	1	2	3	4
5. How much do they let you down when you are counting on them?	1	2	3	4
6. How much do they get on your nerves?	1	2	3	4

7. How close is your relationship with your spouse or partner?

Tick <u>one</u> box

Very close ☐

Quite close ☐

Not very close ☐

Not at all close ☐

1	2	3	4	5	6	7
Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly agree	Moderately agree	Strongly agree

In the last week I...							
9. ... have had someone to encourage me to participate in physical activity on a regular basis.	1	2	3	4	5	6	7
10. … I have had someone to participate with me in physical activity.	1	2	3	4	5	6	7
11. … I felt supported in having a regular pattern of physical activity.	1	2	3	4	5	6	7

SECTION 8: INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

☐ Yes

☐ No → ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include travelling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

_____ **days per week**

☐ No vigorous job-related physical activity → ***Skip to question 4***

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

_____ **days per week**

☐ No moderate job-related physical activity → ***Skip to question 6***

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

☐ No job-related walking → ***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day**
_____ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

☐ No travelling in a motor vehicle → ***Skip to question 10***

9. How much time did you usually spend on one of those days **travelling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day**
_____ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No bicycling from place to place → ***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**
_____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No walking from place to place → ***Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**
_____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

☐ No vigorous activity in garden or yard → ***Skip to question 16***

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

☐ No moderate activity in garden or yard → ***Skip to question 18***

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

☐ No moderate activity inside home → ***Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day**
_____ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

☐ No walking in leisure time → ***Skip to question 22***

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day**
_____ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

☐ No vigorous activity in leisure time → ***Skip to question 24***

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **days per week**

☐ No moderate activity in leisure time → ***Skip to PART 5: TIME SPENT SITTING***

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?
_____ **hours per day**
_____ **minutes per day**

PART 5: TIME SPENT SITTING

These questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ **hours per day**
_____ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ hours per day
_____ minutes per day

PART 6: PHYSICAL ACTIVITY SELF-EFFICACY SCALE

These questions will help us understand your confidence in your ability to change your level of physical activity. Please circle which answer applies to you for each question. If you are *very uncertain* circle 1, *rather uncertain* circle 2, *rather certain* circle 3, and *very certain* circle 4.				
	Very uncertain	**Rather uncertain**	**Rather certain**	**Very certain**
How certain are you that you could overcome the following barriers? I can imagine to carry out my exercise intentions, ...				
... even when I have worries and problems.	1	2	3	4
... even if I feel depressed.	1	2	3	4
... even when I feel tense.	1	2	3	4
... even when I'm tired.	1	2	3	4
... even when I am busy.	1	2	3	4

Thank you for completing this questionnaire. Please hand the questionnaire to Pamela Flynn when she next visits.

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).