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A FEASIBILITY STUDY TO ASSESS THE DELIVERY OF A LIFESTYLE INTERVENTION (TREATWELL) FOR COLORECTAL CANCER PATIENTS UNDERGOING POTENTIALLY CURATIVE TREATMENT.

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ABSTRACT

Objectives To assess the feasibility of delivering and evaluating a lifestyle programme for colorectal cancer patients undergoing potentially curative treatments.

Study design Non-randomised feasibility trial

Setting NHS Tayside

Participants Adults with stage I to III colorectal cancer

Intervention The programme targeted smoking, alcohol, physical activity, diet and weight management. It was delivered in 3 face-to-face counselling sessions (plus 9 phone calls) by lifestyle coaches over three phases (1 - pre-surgery, 2 - surgical recovery and 3 - post treatment recovery).

Primary outcome Feasibility measures (recruitment, retention, programme implementation, achieved measures, fidelity, factors affecting protocol adherence and acceptability).

Secondary outcomes Measured changes in body weight, waist circumference, walking and self –reported physical activity, diet, smoking and alcohol intake, fatigue, bowel function and Quality of Life (QoL).

Results Of 84 patients diagnosed, 22 (26%) were recruited and 15 (18%) completed the study. Median time for intervention delivery was 5.5 hours. Coaches reported covering most (>70%) of the intervention components but had difficulties during phase 2. Evaluation measures (except walk test) were achieved by all participants at baseline, and most (<90%) at end of phase 2 and phase 3, but <20% at end of phase 1. Protocol challenges included limited time between diagnosis and surgery and the presence of co-morbidities. The intervention was rated highly by participants but limited support from NHS staff was noted. The majority of participants (77%) had a BMI >25kg/m^2 and none were underweight. Physical activity data showed a positive trend towards increased activity overall but no other changes in secondary outcomes were detected.

Conclusions Further research is required to optimise recruitment and evaluate more appropriate assessment tools. Protocols for phase 2 and 3 need flexibility to allow for variation in clinical progress. Ways for NHS staff to facilitate the programme should be explored.

Trial registration number ISRCTN 52345929

STRENGTHS AND LIMITATIONS

- This feasibility study is the first to have offered a comprehensive lifestyle intervention programme at diagnosis with support before, during and after treatment in patients with colorectal cancer.
- The study highlights the wide range of variables that need to be considered in designing a future randomised controlled trial (including recruitment and support from NHS staff, complexities of patient health status and time required for permissions, assessment and interventions).
- The lack of randomisation means it is not possible to estimate uptake to a randomised controlled trial.
- The work was undertaken in a single NHS health board and may not be representative of other treatment centres.

COMPETING INTEREST STATEMENT

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work other than the Chief Scientist Office who funded the award, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

ETHICS, CONSENTS AND PERMISSIONS

Ethical approval was provided by the East of Scotland Research Ethics Service, REC reference no. 13/ES/0153. All participants provided written, informed consent.

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AUTHORS' CONTRIBUTION

All authors have made substantial contributions to the study conception and design, and the development and editing of the manuscript. MM led initial study design and development, assisted with data collection, carried out the analyses and drafted the initial draft manuscript; RJCS had the initial concept and led initial study design and development; RO'C led the fidelity assessments (development and analyses) and provided guidance on project progression; MW had the initial concept and led initial study design and development; AC contributed to study design; JS carried out the day to day management of the study and led the data collection; JR contributed to study design; MS and JMcK led on qualitative assessments (development and analyses); ASA had the initial concept and led initial study design and development, contributed to data analyses and had oversight of the study.

All authors have read, edited and approved the manuscript for publication.

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DATA SHARING

Technical appendix, statistical code, and dataset available from the authors on request.

INTRODUCTION

Colorectal cancer (CRC) survival has improved in the last decade due to earlier diagnosis and new treatments but, in Scotland, survivors still have notable excess mortality within the ***first year post diagnosis*** compared to other European countries [1]. Survivors also have a high rate of pre-existing co-morbidities and treatment related symptoms. The latter are experienced by 15% undergoing colonic surgery, 33% with rectal surgery, 50% of those with chemo-radiation therapy and 66% of patients undergoing short course radiotherapy. These symptoms include fatigue, physical discomfort and bowel function problems [2].

In people diagnosed with cancer it is recognised that smoking cessation, improved physical activity and diet have the potential to impact on treatment outcomes and cancer recurrence. A number of studies have demonstrated that higher levels of physical activity are associated with better physical functioning [3] and reduced fatigue [4]. Follow up studies report better disease free, recurrence free and overall survival in people who are more physically active [5, 6]. Intervention trials have shown that higher levels of physical activity initiated at pre-habilitation (pre surgery), post-surgery, during and after adjuvant therapies (re-habilitation) [7-9] are associated with improved cardiorespiratory fitness, muscular strength, physical functioning, quality of life, and reduced psychosocial distress.

There is growing evidence for the impact of diet on CRC cancer outcomes. A large observational study has reported that a higher level of a Western dietary intake (compared to a lower level of Westernisation) resulted in lower disease-free and overall survival rates [10]. At intervention level, a trial of dietary counselling delivered during treatment [11] showed that nutrition improvements were associated with reduced treatment related co-morbidity (radiotherapy toxicity) at ***3 months*** and after a mean follow up of 6 years. Three post-treatment exploratory trials [12-14] of combined lifestyle interventions have reported improved dietary behaviour, reduced fatigue, improved exercise tolerance, functional capacity and quality of life.

There is some evidence to support lifestyle interventions in the pre-surgical and post- treatment periods, but no trial has yet evaluated an intervention covering the full patient journey. Patients report confusion about appropriate lifestyle behaviours because they have received conflicting advice at different treatment stages and rarely receive personalised support in the period after treatments end and during return to normal health [15]. It has been noted that relatively few CRC patients stop smoking after diagnosis (13.7% pre-diagnosis to 9% 5 months later) [16]. Current data suggest that, in CRC patients, physical activity levels drop significantly by 6 months post-diagnosis [17]. This may reflect lack of consistent guidance from clinicians, and patient confusion over the merits of rest versus activity [15]. Similarly, for diet, misconceptions exist over body weight gain (or loss) and understanding of appropriate food selection.

There are a number of behavioural frameworks that could support lifestyle change from the start of care such as the concept of the “teachable moment” [18]. Cancer care clinicians, starting at diagnosis and throughout the cancer pathway, can be powerful advocates to help patients understand the importance of a healthy lifestyle and they have expressed interest in providing guidance [19]. Patients consider information obtained from cancer specialists to be of the best quality [20]. Despite major concerns over

their diagnosis many patients request advice on what might be done to prepare for surgery and there is a need for clinicians to identify an effective programme with the potential to improve health in the first year after diagnosis. Increasingly, asymptomatic patients are diagnosed via the national bowel screening programme which means that this patient group is less frail than those diagnosed late and have considerable potential to initiate lifestyle change. Opportunities in the "pre-habilitation" period have been highlighted in cancer strategy documents [21] but little is known about likely uptake of interventions.

This study aimed to assess the practical aspects of delivering and evaluating a lifestyle intervention programme (TreatWELL) for CRC patients undergoing potentially curative treatments in order to inform the feasibility of undertaking a randomised controlled trial (RCT) to assess the clinical and cost-effectiveness of this intervention at one year after diagnosis.

Specific objectives were to assess recruitment and retention to assist in the design of a future RCT, assess the feasibility of data collection procedures, ease of programme implementation, patient acceptability, fidelity and factors influencing adherence to the intervention.

METHODS

Study design and setting

This study was a single arm, two-centre feasibility study of the TreatWELL intervention programme carried out in tertiary level teaching hospitals in Tayside, UK.

Sample size

We aimed to recruit 34 participants in order to be able to assess feasibility objectives and to provide data to inform the sample size required to show significant differences in health outcome variables in a fully powered RCT. These numbers were based on a pragmatic assessment of patient numbers, eligibility and participation based on a previous study undertaken with the same patient group (at post-treatment stage) in the same geographic area [13].

Eligibility

Eligible patients were adults aged >18 years , capable of giving informed consent, considered to have stage I to III colorectal cancer, eligible for potentially curative treatment (had to be fit for major surgery). Patients who had severe cognitive impairment, emergency surgery or pre-operative neo-adjuvant therapy were excluded from the study.

Recruitment

Eligible patients were introduced to the study by a clinical nurse specialist (CNS) after discussing treatment and care plans following a cancer diagnosis. At this meeting the CNS introduced the study and endorsed its importance for helping to achieve lifestyle change in the pre-surgical period. Interested patients were provided with a participant information sheet, an invitation and endorsement letter from the lead CRC clinician for Tayside and a pre-paid opt-in reply slip which they could return to the research team. A research nurse (RN) then contacted patients, who had either provided their contact details to the CNS or returned the pre-paid reply slip, to discuss the study in detail and (if appropriate) make an appointment to obtain written informed consent and take baseline measurements. This appointment was

held at the referring hospital or the participant's home if a hospital location was reported as a barrier to participation.

Intervention

The TreatWELL intervention programme aimed to facilitate collaboratively agreed behaviour changes towards achieving and maintaining smoking cessation, increased physical activity (to at least 150 minutes moderate intensity activity per week), caloric intake appropriate to weight status and a nutrient dense diet. All goals were consistent with the American Cancer Society and World Cancer Research Fund guidance for cancer survivors [22, 23]. The behavioural approaches were informed by two main theoretical frameworks: self-regulatory theory [24] and the health action process approach [25].

Following baseline measures consented patients' contact details were passed to a Lifestyle Coach (LC) who then commenced the TreatWELL personalised intervention. The LCs had a nursing background, experience with cancer patient management and underwent a 3 day bespoke training programme covering smoking cessation, increasing moderate physical activity, brief interventions on alcohol and weight management (post-surgical and post treatment). The intervention was delivered via three face-to-face contacts (one per intervention phase and a minimum of 9 phone calls) supported by written literature and a range of behavioural techniques.

- Phase 1 Pre-habitation to start within 3-10 days of diagnosis to surgery
- Phase 2 Surgical recovery to start 1 day post-op and aim to complete within 21 days
- Phase 3 Post-surgical / adjuvant therapy recovery to start 21 days post-op for 25 weeks

The total intervention period comprised 31 weeks although duration was flexible as it was based on the individual's treatment regimen. Decisions about phase completion (e.g. defining the end of post-surgical recovery) and progression was agreed in conjunction with the CNS. At each phase of the programme, personalised, specific goals were identified with a focus on two health behaviours that were selected as a priority for that individual (e.g. smoking, physical activity). All participants were invited to engage a support person (e.g. spouse) to assist in their adherence with the programme. (Appendix 1).

Participants were encouraged to develop personalised action and coping plans. Activities (e.g. brisk walking) were demonstrated and tried by participants. Access to an equipment tool kit (pedometers, resistance bands and DVDs) was also offered. Emphasis was placed on self-monitoring and goal setting, e.g. physical activity through pedometers, with weekly feedback in the first week of each phase. In phase 2, participants were encouraged to commence activity in accordance with ability, their post-op condition and guidance from their health care team. In Phase 3, the participant's Phase 1 plan was repeated and expanded to include an emphasis on core strength, mobility and functional ability, with a strict protocol for referral to a physiotherapist if there were any safety concerns.

In phase 1, advice for participants not at risk of malnutrition (BMI>20kg/m^2) focused on avoiding weight gain and increasing nutrient quality of their diet in line with the Department of Health Eatwell guide [26]. Participants were also advised about decreasing alcohol intake, as appropriate. No energy prescription was set in phase 1. In phase 2 and initially in phase 3, nutrition advice focused on symptom management (e.g. anorexia, vomiting and bowel problems) and worked towards achieving a nutrient dense diet. In the later stage of phase 3, all participants (BMI>20kg/m^2) were given personalised guidance on a nutrient dense diet and avoidance of excess weight gain. Participants with a BMI>25kg/m^2 were advised on

avoidance of weight gain and modest weight reduction (>5% weight loss) using a personalised energy prescription goal. Communications emphasised the concept of building resilience through the combined approach of increasing muscle mass (through physical activity) and decreasing excess body fat (through caloric reduction). The importance of regular self-weighing was stressed and feedback provided at each telephone consultation.

Informed by behaviour change techniques used in previous interventions [27] and the behaviour change wheel [28], a range of evidence-based behavioural techniques were employed to motivate and support lifestyle change. These included motivational interviewing, formation of specific implementation intentions, self-monitoring, personalised action and coping plans, feedback and re-enforcement.

Measurements

The research nurses prospectively collected details on socio-demographic background, clinical information (including tumour stage and site), type of surgery, stoma status, medications and details of adjuvant treatments.

Primary Outcome Measures

Recruitment and retention were assessed from research nurse records. Information on reasons why patients were ineligible or choose not to participate were recorded with patient consent.

Programme implementation (by LCs) was estimated from a structured pro-forma completed after every patient contact which recorded actual values or scaled ratings on:

- Intervention start time (days after diagnosis)
- Total contact time
- Ease or difficulty of implementing the session
- Perceived fidelity to the intervention content
- Extent of patient engagement, receptivity and motivation

Achieved measurements (by RNs) were recorded at baseline and the end of each phase of the study.

Participants views on acceptability of the intervention and factors influencing adherence were assessed by in-depth qualitative interviews transcribed and analysed using a thematic framework approach. Participants (n=10), stratified by degree of engagement with the intervention, were invited for interview at the end of phase 2 and another 10 participants at the end of phase 3.

Secondary outcome measures

Anthropometric measures were taken as follows:

- Body weight measured with the participant wearing indoor clothing and no shoes, using a calibrated Seca 877 digital scale.
- Height measured with a Seca Leicester portable stadiometer.
- Body mass index (BMI) was calculated – weight (kg)/height (m)^2.
- Waist circumference measured with a Seca 201 measuring tape, with the participant in the standing position and the tape positioned midway between the lateral lower rib margin and the iliac crest. If these landmarks could not be identified, the measurement was taken at the level of the umbilicus. Two measurements were taken post-exhalation and the mean recorded.

Smoking status was self-reported and alcohol intake was measured using 7 day alcohol recall [29] – units of alcohol consumed per week and number of alcohol free days per week were noted.

Dietary intake was measured using the dietary instrument for nutrition education (DINE) questionnaire [30].

Physical activity was assessed using the International Physical Activity Questionnaire [IPAQ] short form [31] and the 6 minute walk test [32].

Health outcomes of interest were explored - fatigue was measured using the multidimensional fatigue inventory (MFI-20) [33] and physical function and quality of life by the EORTC GLQ C30 Quality of Life questionnaire for bowel cancer patients and the EORTC GLQ C29 Quality of Life questionnaire for colorectal cancer patients [34]. Bowel function was assessed by the Low Anterior Resection Syndrome Score (LARS) [35].

Data analysis

Descriptive statistics allowed characterisation of the cohort. Outcome measures were assessed for completeness but no statistical analysis was undertaken given the small sample which was not powered to show definitive results.

Data from proformas completed by the LC were analysed by descriptive statistics (mean ± SD) to estimate completeness of delivery and areas for improvement, and to provide contextual information (including NHS service issues) on patient engagement.

All participant interviews were recorded, transcribed and analysed using a thematic framework approach to explore patients' views on recruitment and delivery acceptability, patient engagement with the intervention, and likely facilitators and barriers to conducting a full RCT.

RESULTS

Recruitment and retention

Over the 7 month recruitment period (01.04.14 to 31.10.14) the number of patients diagnosed and recorded with colorectal cancer was 84 and 22 (26%) were recruited to the study (Figure 1). Of the remainder, 17 were ineligible, unfit or not approached to participate and 45 declined to take part, the most common reason was the extra burden of the study. The median age of non-participants was 74 (range 44 to 90 years) and 49% were male (Table 1). Of the 22 who were recruited, 15 (68%) completed the study (Figure 2). The main reason for drop out at all stages was major ill health.

Table 1 Baseline demographic and clinical characteristics by completion[#]

	Recruited n=22	Completed n=15	Dropped out/lost to follow up n=7
Male Gender	17 (77%)	11 (73%)	6 (86%)
Age: Median (LQ, UQ)	67.0 (60.0, 74.3)	66.0 (60.0, 72.0)	75.0 (64.0, 80.0)
Baseline BMI (kg/m^2): Median (LQ, UQ)	28.3 (25.5, 33.5)	28.6 (26.1, 33.6)	25.8 (24.1, 32.6)
SIMD Category*			
1-3 (most affluent?)	5 (23%)	4 (27%)	1 (14%)
4-7	10 (45%)	7 (46%)	3 (43%)
8-10 (most deprived?)	7 (32%)	4 (27%)	3 (43%)
Smoking Status			
current	2 (9%)	1 (7%)	1 (14%)
ex-smoker	14 (64%)	10 (67%)	4 (57%)
never smoked	6 (27%)	4 (26%)	2 (28%)
Treatments			
Chemotherapy & radiotherapy	3 (14%)	2 (13%)	1 (14%)
Chemotherapy only	6 (27%)	5 (33%)	1 (14%)
No oncology	10 (45%)	8 (53%)	2 (29%)
Palliative care	3 (14%)	0 (0%)	3 (43%)
Cancer staging			
Duke A	3 (14%)	3 (20%)	0 (0%)
Duke B	6 (27%)	3 (20%)	3 (42%)
Duke C	8 (36%)	6 (40%)	2 (29%)
Squamous cell carcinoma	2 (9%)	2 (13%)	0 (0%)
Well differentiated neuroendocrine	1 (5%)	1 (7%)	0 (0%)
Metastases	2 (9%)	0 (0%)	2 (29%)

All results are n (%) unless stated otherwise

*SIMD Scottish Index of Multiple Deprivation

Programme Implementation

The median time in phase 1 (pre-habilitation) was 15 days. The median time in phase 2 was 36.5 days and phase 3 was 102 days but was frequently extended by clinical problems due to health status post-surgery, treatment responses and pre-existing co-morbidities. Table 2 illustrates the significant and varied challenges experienced by individual participants during the recovery phase. Many patients did not have sufficient time in phase 3 (prior to project end) to enable secondary outcomes to be reliably assessed.

Table 2 Summary of participants' clinical progress during the TreatWELL study

Participant completed study n= 15 Dropped out n=7

1	Biopsy showed advanced disease after patient had undergone baseline measures and the phase 1 LC intervention visit. Patient excluded from further study measures.
2	Surgery as planned but poor postoperative recovery and discharged to a continuing care unit. Intravenous (IV) chemotherapy started after discharge home followed by oral chemotherapy and radiotherapy. Waiting for stoma reversal. All phases of study completed.
3	Surgery as planned. Slow recovery post-surgery and on parenteral nutrition. No adjuvant therapies required. Discharged home with carers twice a day, walking with a Zimmer frame. May have further surgery and did not progress beyond phase 2 in study. Seen at peripheral hospital.
4	Surgery as planned. No adjuvant therapies required. Became worried about recurrence after discharge and had to have psychological support. Hip pain re-started in phase 3. Lung metastases and heart failure diagnosed. Dropped out during phase 3. Patient died.
5	Surgery as planned. No adjuvant therapies required. All study phases completed.
6	Short phase 1. Emergency surgery to de-function bowel (stoma formation). Successful chemotherapy and radiotherapy before main surgery. Phases 2 and 3 switched round for this participant. All study phases completed.
7	Surgery as planned then admission to high dependency unit post-operatively. Discharged but re-admitted for further surgery and stoma formation. Chemotherapy given. All study phases completed.
8	Surgery performed. Further surgery performed for removal of residual tumour. Stoma reversed. No adjuvant therapies required. All study phases completed.
9	Biopsy showed advanced disease after patient had undergone baseline measures. Patient not going ahead for surgery and excluded from further study measures.
10	Surgery as planned and chemotherapy. Admitted with diabetic ketoacidosis but diabetes since resolved. Slow recovery. Phase 1 delivered day before surgery Phase 2 and 3 of study completed.
11	Short phase 1. Surgery performed. No adjuvant therapies required.. Completed phase 2 and 3 of the study.
12	Phase 1 delivered day before surgery. Surgery performed. Chemotherapy commenced early due to cancellation in clinic and completed. Phase 2 completed. Wife has health issues which prevented him completing phase 3.
13	Surgery as planned, No adjuvant therapies required. All phases of study completed. Home visits.
14	Surgery as planned and chemotherapy started after surgery. All study phases completed. Seen at peripheral hospital.
15	Surgery as planned and no chemotherapy required. All phases of study completed (short phase 1).Home visits.
16	Surgery as planned, No adjuvant therapies required. All phases of study completed. Home visits.

17	Surgery as planned. Oral chemotherapy after surgery. All phases of study completed.
18	For de-functioning stoma and pre-surgery radiotherapy and chemotherapy. Surgery performed. Lost to follow up as still requiring intensive treatment at study end (phase 1 and 2 only).
19	Surgery as planned but re-admitted. Slow recovery from surgery with significant complications. Phase1, 2 and 3. Dropped out of study during phase 3 as felt back to normal and did not require further support.
20	No phase 1 undertaken. Surgery as planned, long post-operative recovery. No adjuvant therapies required. Phase 2 and 3 of study completed.
21	Surgery performed. No adjuvant therapies required. All phases of study completed. Home visits.
22	Phase 1 delivered day before surgery. Surgery performed. Chemotherapy required. Phases 2 and 3 of study completed.

Total median intervention delivery by lifestyle counsellors was 5 hrs 29 mins. LCs reported that patient engagement was high, with 93-100% being at least "fairly engaged" at all stages. Similarly the LCs reported that participants were receptive and interested in the information being delivered.

LCs rated participants as at least "fairly motivated" to improve diet and physical activity levels. During the immediate recovery stage (phase 2) LCs were most likely to report goal setting for diet and PA as "neither easy nor difficult" (73% and 64% for diet and PA respectively). At the phase 3a time point, LCs rated the ease of goal setting more favourably, with 46% of consultations described as "easy" to set dietary goals and 82% for PA.

Achieved Measurements

Baseline measures were completed on all participants, except in four cases, where the 6 minute walk test had to be excluded due to lack of space in the participant's home. Only 6 out of 33 participants were seen at the end of phase 1 due to the difficulty in fitting in visits prior to surgery. All participants remaining in the study were seen at the end of phase 2, but it was not possible to carry out all anthropometric measurements and walking tests at this point. Walking tests were not possible at the end of phase 3. Questionnaire data were generally well completed however some participants were reluctant to answer sexual function questions (LARS questionnaire) in all phases.

Factors affecting protocol adherence

The LCs reported that they were able to cover most of the intervention components during phase 1 (78% delivery), 3a (73% delivery) and 3b (90% delivery). However, during the post-surgical phase (phase 2), LCs reported difficulties with access to patients. Lifestyle counselling was reported as most challenging during visits 1 (first contact) and 2 (immediately post-surgery). Delivery became more comfortable towards the end, with LCs reporting 70% of the final sessions as "fairly easy" (compared with 39% in Phase 1 and 46% in Phase 2).

The major challenges of intervention delivery reported by the LCs were:

- The short time between diagnosis and surgery

- Participants identifying time to fit in the baseline and intervention visits in addition to diagnostic and treatment preparation schedules
- Seeing patients in phase 2 (short period)
- Difficulties identifying the transition from end of phase 2 and start of phase 3
- Poor clinical progress (some patients were readmitted)
- Due to complications a longer treatment period was required which extended phase 3 beyond the project life
- Mixed messages from NHS staff and TreatWELL LCs

Participants views on acceptability

Of 20 participants who completed phase 2, 14 were invited for interview, 3 declined and 11 participated (7 men and 4 women), with a mean age of 66 ± 6 (range 57 to 75) years. Interviewees were from a range of areas of deprivation.

Most participants recalled that they had been recruited around the time of their diagnosis. For some, this timing appeared to have facilitated participation, as the study offered a potentially beneficial experience on which to focus, taking their mind off their diagnosis and concerns for the future. Several were reassured by the endorsement of colorectal consultants. Generally, the amount of contact, and the balance between visits and telephone calls, appeared acceptable, and the provision of home visits was particularly appreciated. Some appeared a little apprehensive about the prospect of 'going it alone' at the end of the study but they recognised that its end signalled another milestone in their recovery. Participants spoke positively of LCs and felt that LCs had been able to move them gently into doing things they might have been reluctant to do. Some hinted that they had relied on the counsellor for wider emotional support.

The PA advice appeared to have been particularly salient, with most participants being able to describe their PA goals and targets. Pedometers were felt to have been very helpful. Some described having become so fixed on their PA goals that they "over-did things", but most felt that the advice had encouraged them to be more active and to "push" themselves more than they might otherwise have done. Participants generally felt that they had managed to take on board the diet advice, although some had struggled with cutting out 'treats'.

A number of facilitators and barriers to engagement were identified. Prior enjoyment of walking and previous experience of weight loss programmes were both beneficial, as were supportive family members who encouraged adherence to healthy eating and sometimes participated in activity along with the participant. Receiving a diagnosis of cancer was a major motivator for adherence. Participants were determined to overcome their diagnosis and quickly regain their health, not least for significant others. Similarly, participants were motivated to make changes in order to put themselves in the best condition for surgery and to optimise their recovery. One woman was motivated to maintain a healthy weight during her stay in hospital by witnessing fellow patients who were overweight struggling with their mobility. Monitoring progress especially with regard to levels of PA also provided motivation and some enjoyment for participants.

A main factor which negatively affected adherence to the intervention was participants' physical health. Some participants felt too unwell to increase PA, although this was alleviated for some by building

strength gradually, whilst others described comorbidities hampering their attempts to be physically active.

Some clinical staff were reported to have advised participants to gain weight by eating whatever they liked and by not discouraging unhealthier foods, in direct contrast to TreatWELL. This inconsistency caused confusion, and participants reported following the advice of clinical staff. Participants also highlighted that NHS staff had little awareness of TreatWELL and appeared to provide little encouragement. More generally, it was noted that nursing staff did not encourage patients to get up and move on the ward.

Secondary Outcomes

There was no change in smoking habits – one of the two smokers at baseline was lost to follow-up and the other smoker continued to smoke. The number of participants who reported consuming alcohol decreased between baseline and end of phase 3 although in some individuals intake increased. PA data shows a positive trend towards increased activity overall. For the 15 who completed the study, minutes of physical activity nearly doubled from a median of 480 (IQ range 240 – 720) per week to 840 (IQ range 330 to 1260). This was largely due to an increase in leisure time activities, but, a decrease in active time at work (few participants continued to work during the study period). Dietary data indicated no increase in total fat score but a desirable increase in fibre score. Quality of Life data indicated some increase in global health function but also increases in anxiety.

The majority of participants had excess weight (77%) and 40% were obese at baseline (Table 1). None were underweight. At the end of phase 2, body weight had decreased as expected in the post-surgical period. Despite this weight loss, no underweight individuals were detected at the end of phase 3 and the proportion with excess weight remained. The 6 minute walk test indicated no decrease in functional ability by the end of phase 3.

It should be noted however, that all secondary outcome results were obtained principally to test ability to undertake measures and are not powered to detect differences.

DISCUSSION

Whilst it is recognised that pre-surgical (prehab) lifestyle intervention may have significant impact on improving health outcomes in the early months following a diagnosis of colorectal cancer there is little evidence of multi-component intervention RCTs to support investment in this area. This study illustrates the complexities of delivering and evaluating such interventions and highlights issues that need to be addressed prior to progressing further work. The main findings show that it is difficult to recruit at diagnosis because of the multitude of investigations taking place, the staff's perceptions of frailty and age (although all participants were deemed fit for surgery) and the relatively short period available for recruitment, baseline data collection and intervention delivery before surgery. Phase 2 was predictably short for most patients, but longer in those who had previous illness or had developed post-surgical complications. It should be noted that because patients were recruited at diagnosis, the extent of the disease (i.e. stage) was unknown and complications were unpredictable. Many participants spent insufficient time in phase 3 (prior to study end) for the impact of the intervention to be assessed, highlighting the need for a longer study duration for final outcome measurements. The clinical pathways of participants were unpredicted and impacted on study retention. The hardest challenge in delivery was when to introduce the next phase of the intervention (phase 2 to phase 3) because many participants had

complex journeys through treatment. These findings highlight that compliance with a strict RCT protocol for this type of intervention is likely to be difficult. Outcome measures were largely acceptable, although consideration should be given to whether the more sensitive questions on quality of life are required. Participant views suggest the intervention was largely acceptable, and that the focus on physical activity was appropriate. The high number of patients with excess body weight at study recruitment (and exit) is of concern and a future trial encompassing weight loss is likely to need long term support and follow up.

This study (to the best of our knowledge) is the first to have offered a comprehensive lifestyle intervention at diagnosis with support before, during and after treatment in patients with colorectal cancer. Although the study is small and was undertaken in a single NHS health board, the results have highlighted a wide range of issues that would need to be addressed in a full trial of a multi-component intervention. The lack of randomisation means that it is not possible to assess whether uptake to a randomised trial with control condition would be similar.

Moug et al [36] have recently reviewed 14 randomised controlled trials in this patient group and concluded that lifestyle interventions are feasible in patients with CRC. However, it is notable that there were no RCTs of tobacco and alcohol. In general, they reported variable recruitment rates but good adherence and retention (as is the case in our own study). Ravasco et al [11] have demonstrated positive outcomes in CRC patients referred for radiotherapy (irrespective of other therapies provided) after dietary counselling. However, other trials of diet and lifestyle have been focussed on patients after the end of treatment [14, 37, 38]. The challenges to conducting a trial in this patient group are similar to those described by Hubbard et al [39] in feasibility work of a pragmatic RCT for a group based rehabilitation programme for CRC survivors which reported a high likelihood of recruitment bias, potential of sub-optimal completion of outcome data, missing data and poor intervention adherence.

The current intervention approach is ambitious, but could be refined for testing in an RCT if all visits can be linked more closely with clinical appointments, measurement visits are reduced and if the clinical team were encouraged to help support lifestyle changes. Fundamentally interventions being tested should be scalable, durable and cost effective [40]. Whilst there is much practical guidance on diet and lifestyle for cancer survivors [41, 42] and interventions which have been demonstrated to be safe and feasible there remains a need for studies that can demonstrate the impact of lifestyle intervention on disease outcomes. Research in this area requires multilevel approaches with full support from health service staff (both in recruitment and support for lifestyle action), intervention staff for the delivery of tailored, personalised approaches and patient interest and advocacy.

CONCLUSIONS

Further work is needed to optimise recruitment and measurements. Protocols for phase 2 and 3 need to be flexible to allow for variation in clinical progress. Ways for NHS staff to support and facilitate the programme aims should be explored.

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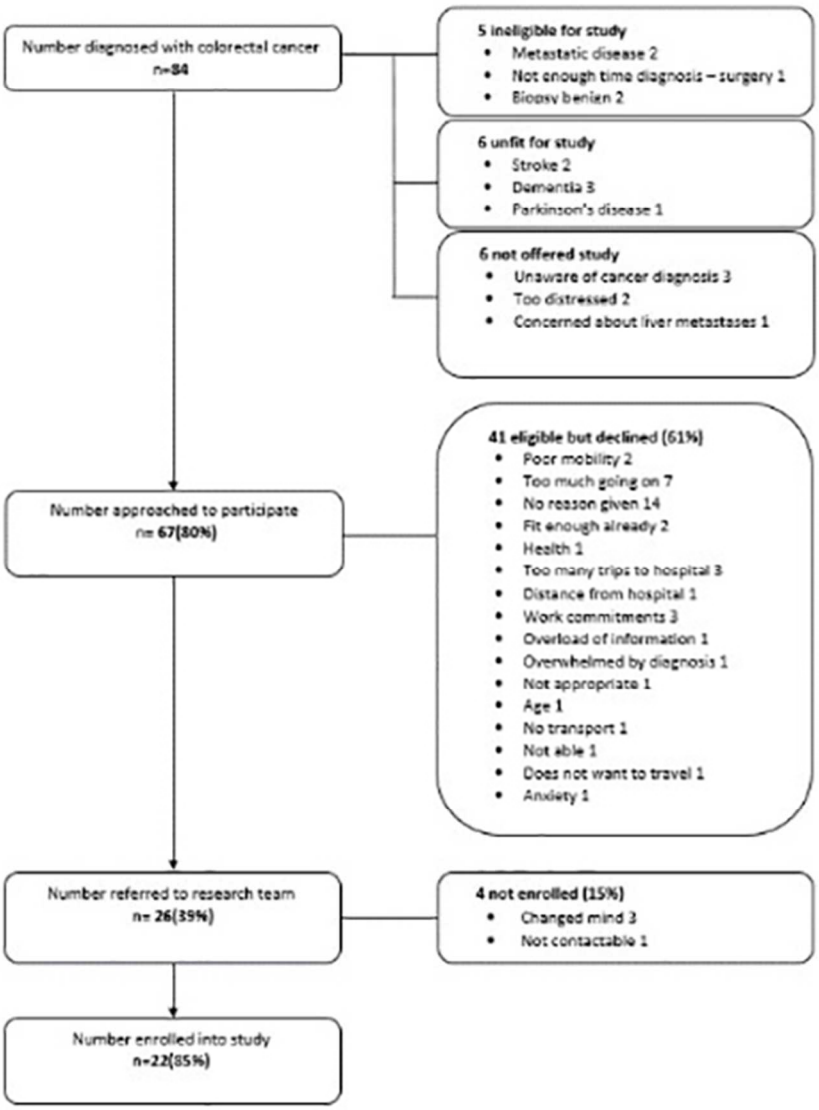

Figure 1 TreatWELL recruitment CONSORT flowchart

46x64mm (300 x 300 DPI)

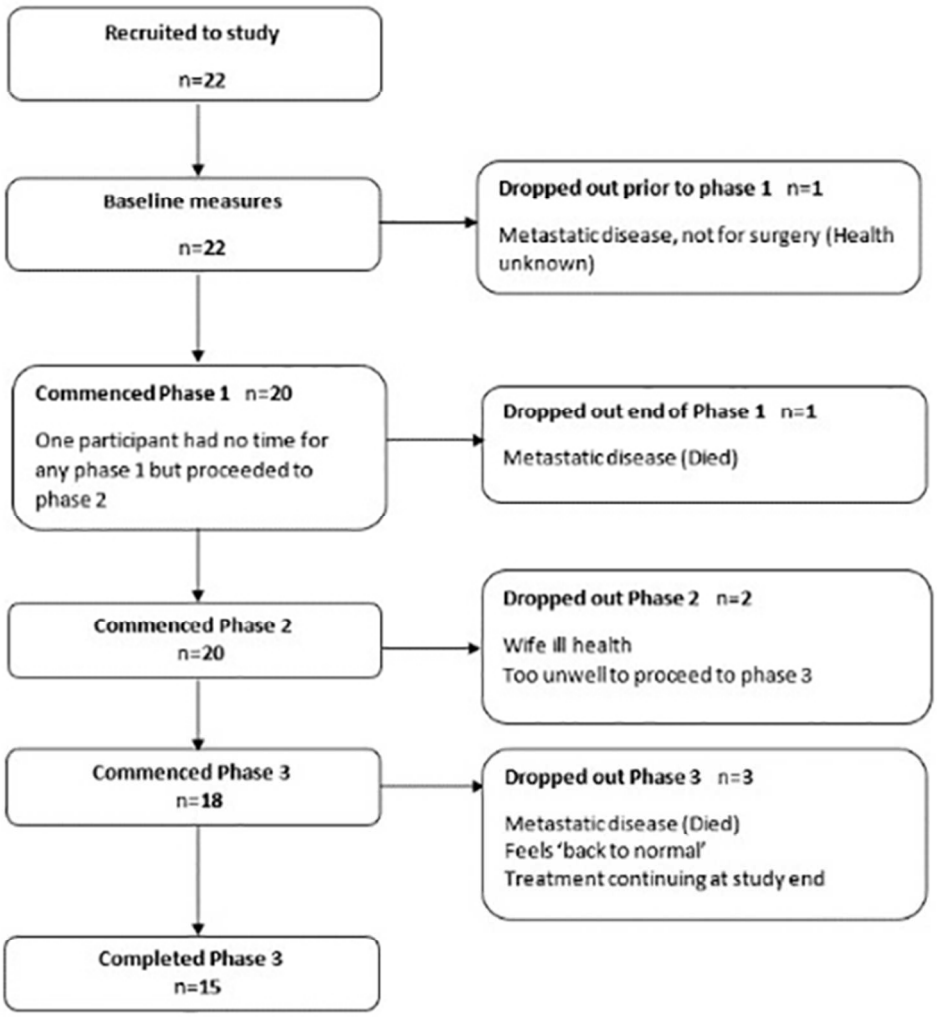

Figure 2 TreatWELL study progression CONSORT flowchart

55x59mm (300 x 300 DPI)

Appendix 1 TreatWELL intervention delivery plan and resources

Phase 1 Prehabilitation

a) Delivery mode:

Face to face study consultation visit 1 (1 hour) (hospital/research centre). All participants were encouraged to bring a support friend/family member

Consultation Focus:

Getting fit for surgery

- Education and endorsement on smoking, alcohol, physical activity, fruit and vegetables (FAV))

Resources:

- Fast track smoking cessation card
- Leaflet *How to stop smoking and stay stopped* booklet
- AUDIT alcohol assessment
- NHS Scotland alcohol booklet: *Making a Change*
- Macmillan DVD and booklet on physical activity
- DoH physical activity guidelines
- Pedometer

Behaviour change techniques

- Motivational Interviewing questions
- Goal setting for 2 health behaviours (smoking, alcohol, physical activity, diet, FAV)
- Implementation Intentions (smoking, alcohol, physical activity, FAV)
- Self-monitoring (activity diary)

AND Telephone home calls (1 to 2) 10-15 minutes (home)

Phase 2 Surgical Recovery

a) Delivery mode:

Brief face to face support meeting (10- 15 min; in hospital ward)

Consultation Focus:

Recovery and continuing support

- Consistent with Enhanced Recovery After Surgery protocol (ERAS)
- Support about relevant post-operative physical activity
- Education and endorsement about diet (regular meals, sugary drinks, FAV)
- Advice offered on smoking and alcohol as appropriate

Resources:

- Bowel Cancer UK booklets: *Eating and Drinking During Treatment, Fibre after Bowel Cancer* (as appropriate),
- Phase 2 activity diary

Behaviour change techniques

Phase 2 (early phase 3)

b) Delivery mode:

Brief telephone/ward contacts 10-15 minutes

Consultation Focus:

Recovery and continuing support

- 1st visit/call Supportive for managing goals
- 2nd visit/call Responding to queries about diet, physical activity, alcohol, smoking

Phase-3 Post surgical/adjuvant therapy/ recovery

a) Delivery mode:

Face to face consultation study visit 2 (1 hour; hospital/ research centre)

Participants not on chemotherapy Visit takes place start of phase 3	**Participants on Chemotherapy** Visit takes place half way through chemotherapy
Consultation Focus: A new start • Diet, Keep active (walk and talk), • Management of weight **Resources**: • Eatwell plate • 7 day food and drink diary • Booklet: *Thinking about becoming more active?* • 12 week activity diary • Resistance bands • NHS Tayside information *Helping you manage your weight* • Information about personalised weight management • Bowel Cancer UK booklet: *Losing Weight Safely* • Weight awareness plan **Behaviour Change techniques** • Goal setting for two health behaviours physical activity, smoking, alcohol, diet • Implementation intentions • Self-monitoring (body weight log)	**Consultation Focus** A new start • Diet, Keep active (walk and talk), • Introduce weight management concepts **Resources**: • Eatwell plate • 7 day food and drink diary • Booklet: *Thinking about becoming more active?* • 12 week activity diary • Resistance bands **Behaviour Change techniques** • Goal setting for two health behaviours physical activity, smoking, alcohol, diet • Implementation intentions • Self-monitoring (body weight log)

Face to face consultation study visit 3 (1 hour; hospital/research centre)

Participants with no chemotherapy Scheduled 4 weeks post consultation study visit 2	**Chemotherapy** Visit takes place at end of chemotherapy
Consultation Focus: • "Future planning" • Education and endorsement on healthy eating, • Reinforce physical activity advice **Resources**: • *TREATWELL Getting active and eating well after Bowel Cancer treatment* • Calories and alcohol information **Behaviour Change techniques**	**Consultation Focus**: • "Future planning" • Management of weight • Education and endorsement on healthy eating • Reinforce physical activity advice **Resources**: • NHS Tayside information *Helping you manage your weight* • Information about personalised weight management • Bowel Cancer UK booklet: *Losing Weight Safely* • Weight awareness plan • *TREATWELL Getting active and eating well after Bowel Cancer treatment* • Calories and alcohol information **Behaviour Change techniques**

And up to 8 Brief telephone calls 10-15 minutes at home

BMJ Open

A feasibility study to assess the delivery of a lifestyle intervention (TreatWELL) for colorectal cancer patients undergoing potentially curative treatment.

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A FEASIBILITY STUDY TO ASSESS THE DELIVERY OF A LIFESTYLE INTERVENTION (TREATWELL) FOR COLORECTAL CANCER PATIENTS UNDERGOING POTENTIALLY CURATIVE TREATMENT.

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ABSTRACT

Objectives To assess the feasibility of delivering and evaluating a lifestyle programme for colorectal cancer patients undergoing potentially curative treatments.

Study design Non-randomised feasibility trial

Setting NHS Tayside

Participants Adults with stage I - III colorectal cancer

Intervention The programme targeted smoking, alcohol, physical activity, diet and weight management. It was delivered in 3 face-to-face counselling sessions (plus 9 phone calls) by lifestyle coaches over three phases (1 - pre-surgery, 2 - surgical recovery and 3 - post treatment recovery).

Primary outcome Feasibility measures (recruitment, retention, programme implementation, achieved measures, fidelity, factors affecting protocol adherence and acceptability).

Secondary outcomes Measured changes in body weight, waist circumference, walking and self –reported physical activity, diet, smoking and alcohol intake, fatigue, bowel function and Quality of Life (QoL).

Results Of 84 patients diagnosed, 22 (26%) were recruited and 15 (18%) completed the study. Median time for intervention delivery was 5.5 hours. Coaches reported covering most (>70%) of the intervention components but had difficulties during phase 2. Evaluation measures (except walk test) were achieved by all participants at baseline, and most (<90%) at end of phase 2 and phase 3, but <20% at end of phase 1. Protocol challenges included limited time between diagnosis and surgery and the presence of co-morbidities. The intervention was rated highly by participants but limited support from NHS staff was noted. The majority of participants (77%) had a BMI >25kg/m^2 and none were underweight. Physical activity data showed a positive trend towards increased activity overall but no other changes in secondary outcomes were detected.

Conclusions To make this intervention feasible for testing as a full trial, further research is required on a) recruitment optimisation b) appropriate assessment tools c) protocols for phase 2 and 3 which can build in flexibility and d) ways for NHS staff to facilitate the program.

Trial registration number ISRCTN 52345929

STRENGTHS AND LIMITATIONS

- This feasibility study is the first to have offered a comprehensive lifestyle intervention programme at diagnosis with support before, during and after treatment in patients with colorectal cancer.
- The study highlights the wide range of variables that need to be considered in designing a future randomised controlled trial (including recruitment and support from NHS staff, complexities of patient health status and time required for permissions, assessment and interventions).
- The lack of randomisation means it is not possible to estimate uptake to a randomised controlled trial.
- The work was undertaken in a single NHS health board and may not be representative of other treatment centres.

COMPETING INTEREST STATEMENT

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work other than the Chief Scientist Office who funded the award, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

ETHICS, CONSENTS AND PERMISSIONS

Ethical approval was provided by the East of Scotland Research Ethics Service, REC reference no. 13/ES/0153. All participants provided written, informed consent.

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AUTHORS' CONTRIBUTION

All authors have made substantial contributions to the study conception and design, and the development and editing of the manuscript. MM led initial study design and development, assisted with data collection, carried out the analyses and drafted the initial draft manuscript; RJCS had the initial concept and led initial study design and development; RO'C led the fidelity assessments (development and analyses) and provided guidance on project progression; MW had the initial concept and led initial study design and development; AC contributed to study design; JS carried out the day to day management of the study and led the data collection; JR contributed to study design; MS and JMcK led on qualitative assessments (development and analyses); ASA had the initial concept and led initial study design and development, contributed to data analyses and had oversight of the study.

All authors have read, edited and approved the manuscript for publication.

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DATA SHARING

Technical appendix, statistical code, and dataset available from the authors on request.

INTRODUCTION

Colorectal cancer (CRC) survival has improved in the last decade due to earlier diagnosis and new treatments but, in Scotland, survivors still have notable excess mortality within the ***first year post diagnosis*** compared to other European countries [1]. Survivors also have a high rate of pre-existing co-morbidities and treatment related symptoms. The latter are experienced by 15% undergoing colonic surgery, 33% with rectal surgery, 50% of those with chemo-radiation therapy and 66% of patients undergoing short course radiotherapy. These symptoms include fatigue, physical discomfort and bowel function problems [2].

In people diagnosed with cancer it is recognised that smoking cessation, improved physical activity and diet have the potential to impact on treatment outcomes and cancer recurrence. A number of studies have reported that higher levels of physical activity are associated with better physical functioning [3] and reduced fatigue [4] although further work is needed in this area [5]. Follow up studies report better disease free, recurrence free and overall survival in people who are more physically active [6, 7]. Intervention trials have shown that higher levels of physical activity initiated at pre-habilitation (pre surgery), post-surgery, during and after adjuvant therapies (rehabilitation) [8-10] are associated with improved cardiorespiratory fitness, muscular strength, physical functioning, quality of life, and reduced psychosocial distress.

There is growing evidence for the impact of diet on CRC cancer outcomes [11]. A large observational study has reported that a higher level of a Western dietary intake (compared to a lower level of Westernisation) resulted in lower disease-free and overall survival rates [12]. At intervention level, a trial of dietary counselling delivered during treatment [13] showed that nutrition improvements were associated with reduced treatment related co-morbidity (radiotherapy toxicity) at ***3 months*** and after a mean follow up of 6 years. Three post-treatment exploratory trials [14-16] of combined lifestyle interventions have reported improved dietary behaviour, reduced fatigue, improved exercise tolerance, functional capacity and quality of life.

There is some evidence to support lifestyle interventions in the pre-surgical and post- treatment periods, but no trial has yet evaluated an intervention covering the full patient journey. Patients report confusion about appropriate lifestyle behaviours because they have received conflicting advice at different treatment stages and rarely receive personalised support in the period after treatments end and during return to normal health [17]. It has been noted that relatively few CRC patients stop smoking after diagnosis (13.7% pre-diagnosis to 9% 5 months later) [18]. Current data suggest that, in CRC patients, physical activity levels drop significantly by 6 months post-diagnosis [19]. This may reflect lack of consistent guidance from clinicians, and patient confusion over the merits of rest versus activity [20]. Similarly, for diet, misconceptions exist over body weight gain (or loss) and understanding of appropriate food selection.

There are a number of behavioural frameworks that could support lifestyle change from the start of care such as the concept of the “teachable moment” [21]. Cancer care clinicians, starting at diagnosis and throughout the cancer pathway, can be powerful advocates to help patients understand the importance of a healthy lifestyle and they have expressed interest in providing guidance [22]. Patients consider

information obtained from cancer specialists to be of the best quality [20]. Despite major concerns over their diagnosis many patients request advice on what might be done to prepare for surgery and there is a need for clinicians to identify an effective programme with the potential to improve health in the first year after diagnosis. Increasingly, asymptomatic patients are diagnosed via the national bowel screening programme which means that this patient group is less frail than those diagnosed late and have considerable potential to initiate lifestyle change. Opportunities in the "pre-habilitation" period have been highlighted in cancer strategy documents [23] but little is known about likely uptake of interventions.

This study aimed to assess the practical aspects of delivering and evaluating a lifestyle intervention programme (TreatWELL) for CRC patients undergoing potentially curative treatments in order to inform the feasibility of undertaking a randomised controlled trial (RCT) to assess the clinical and cost-effectiveness of this intervention at one year after diagnosis.

Specific objectives were to assess recruitment and retention to assist in the design of a future RCT, assess the feasibility of data collection procedures, ease of programme implementation, patient acceptability, fidelity and factors influencing adherence to the intervention.

METHODS

Study design and setting

This study was a single arm, two-centre feasibility study of the TreatWELL intervention programme carried out in tertiary level teaching hospitals in Tayside, UK.

Sample size

We aimed to recruit 34 participants in order to be able to assess feasibility objectives and to provide data to inform the sample size required to show significant differences in health outcome variables in a fully powered RCT. These numbers were based on a pragmatic assessment of patient numbers, eligibility and participation based on a previous study undertaken with the same patient group (at post-treatment stage) in the same geographic area [15].

Eligibility

Eligible patients were adults aged >18 years , capable of giving informed consent, considered to have stage I to III colorectal cancer, eligible for potentially curative treatment (had to be fit for major surgery). Patients who had severe cognitive impairment, emergency surgery or pre-operative neo-adjuvant therapy were excluded from the study.

Recruitment

Eligible patients were introduced to the study by a clinical nurse specialist (CNS) after discussing treatment and care plans following a cancer diagnosis. At this meeting the CNS introduced the study and endorsed its importance for helping to achieve lifestyle change in the pre-surgical period. Interested patients were provided with a participant information sheet, an invitation and endorsement letter from the lead CRC clinician for Tayside and a pre-paid opt-in reply slip which they could return to the research team. A research nurse (RN) then contacted patients, who had either provided their contact details to the CNS or returned the pre-paid reply slip, to discuss the study in detail and (if appropriate) make an

appointment to obtain written informed consent and take baseline measurements. This appointment was held at the referring hospital or the participant's home if a hospital location was reported as a barrier to participation.

Intervention

The TreatWELL intervention programme aimed to facilitate collaboratively agreed behaviour changes towards achieving and maintaining smoking cessation, increased physical activity (to at least 150 minutes moderate intensity activity per week), caloric intake appropriate to weight status and a nutrient dense diet. All goals were consistent with the American Cancer Society and World Cancer Research Fund guidance for cancer survivors [24, 25]. The behavioural approaches were informed by two main theoretical frameworks: self-regulatory theory [26] and the health action process approach [27].

Following baseline measures consented patients' contact details were passed to a Lifestyle Coach (LC) who then commenced the TreatWELL personalised intervention. The LCs had a nursing background, experience with cancer patient management and underwent a 3 day bespoke training programme covering smoking cessation, increasing moderate physical activity, brief interventions on alcohol and weight management (post-surgical and post treatment). The intervention was delivered via three face-to-face contacts (one per intervention phase and a minimum of 9 phone calls) supported by written literature and a range of behavioural techniques.

- Phase 1 Pre-habitation to start within 3-10 days of diagnosis to surgery
- Phase 2 Surgical recovery to start 1 day post-op and aim to complete within 21 days
- Phase 3 Post-surgical / adjuvant therapy recovery to start 21 days post-op for 25 weeks

The total intervention period comprised 31 weeks although duration was flexible as it was based on the individual's treatment regimen. The delivery mode, consultation focus, resources and behaviour change techniques used in each phase are presented in Appendix 1. Decisions about phase completion (e.g. defining the end of post-surgical recovery) and progression was agreed in conjunction with the CNS. In summary, each phase of the programme comprised verbal educational approaches with written resources (e.g. booklets, resistance bands) and the use of behavioural techniques. Importantly, personalised, specific action goals were identified with a focus on two health behaviours that were selected as a priority for that individual (e.g. smoking, physical activity). All participants were invited to engage a support person (e.g. spouse) to assist in their adherence with the programme. It should be noted that the protocol for phase 3 varied according to whether chemo therapy use. For patients with no adjuvant therapy, the progression to addressing body weight issues (over, under weight and weight loss) was addressed at the start of this phase. For participants undergoing chemotherapy the focus on diet and weight management was delayed to avoid any confusion which might arise with dietary issues related to treatment side effects (e.g. nausea).

Participants were encouraged to develop personalised action and coping plans. Activities (e.g. brisk walking) were demonstrated and tried by participants. Access to an equipment tool kit (pedometers, resistance bands and DVDs) was also offered. Emphasis was placed on self-monitoring and goal setting, e.g. physical activity through pedometers, with weekly feedback in the first week of each phase. In phase 2, participants were encouraged to commence activity in accordance with ability, their post-op condition and guidance from their health care team. In Phase 3, the participant's Phase 1 plan was repeated and

expanded to include an emphasis on core strength, mobility and functional ability, with a strict protocol for referral to a physiotherapist if there were any safety concerns.

In phase 1, advice for participants not at risk of malnutrition (BMI>20kg/m^2) focused on avoiding weight gain and increasing nutrient quality of their diet in line with the Department of Health Eatwell guide [28]. Participants were also advised about decreasing alcohol intake, as appropriate. No energy prescription was set in phase 1. In phase 2 and initially in phase 3, nutrition advice focused on symptom management (e.g. anorexia, vomiting and bowel problems) and worked towards achieving a nutrient dense diet. In the later stage of phase 3, all participants (BMI>20kg/m^2) were given personalised guidance on a nutrient dense diet and avoidance of excess weight gain. Participants with a BMI>25kg/m^2 were advised on avoidance of weight gain and modest weight reduction (>5% weight loss) using a personalised energy prescription goal. Communications emphasised the concept of building resilience through the combined approach of increasing muscle mass (through physical activity) and decreasing excess body fat (through caloric reduction). The importance of regular self-weighing was stressed and feedback provided at each telephone consultation.

Informed by behaviour change techniques used in previous interventions [29] and the behaviour change wheel [30], a range of evidence-based behavioural techniques were employed to motivate and support lifestyle change. These included motivational interviewing, formation of specific implementation intentions, self-monitoring, personalised action and coping plans, feedback and re-enforcement.

Measurements

The research nurses prospectively collected details on socio-demographic background, clinical information (including tumour stage and site), type of surgery, stoma status, medications and details of adjuvant treatments.

Primary Outcome Measures

Recruitment and retention were assessed from research nurse records. Information on reasons why patients were ineligible or choose not to participate were recorded with patient consent.

Programme implementation (by LCs) was estimated from a structured pro-forma completed after every patient contact which recorded actual values or scaled ratings on:

- Intervention start time (days after diagnosis)
- Total contact time
- Ease or difficulty of implementing the session
- Perceived fidelity to the intervention content
- Extent of patient engagement, receptivity and motivation

Achieved measurements (by RNs) were recorded at baseline and the end of each phase of the study.

Participants' views on acceptability of the intervention and factors influencing adherence were explored in in-depth qualitative interviews conducted by MS and JMcK. Interviews were scheduled for around 45-60 minutes and were conducted either face to face or by telephone. Interviews were digitally recorded with participants' consent, and transcribed verbatim for analysis. The original intention was to interview a random sample of one in three participants at the end of phase 2 and another at the end of phase 3. However, because of the low number of participants everyone was invited to take part in an interview towards the end of their journey through the intervention programme.

Secondary outcome measures

Anthropometric measures were taken as follows:

- Body weight measured with the participant wearing indoor clothing and no shoes, using a calibrated Seca 877 digital scale.
- Height measured with a Seca Leicester portable stadiometer.
- Body mass index (BMI) was calculated – weight (kg)/height (m)^2.
- Waist circumference measured with a Seca 201 measuring tape, with the participant in the standing position and the tape positioned midway between the lateral lower rib margin and the iliac crest. If these landmarks could not be identified, the measurement was taken at the level of the umbilicus. Two measurements were taken post-exhalation and the mean recorded.

Smoking status was self-reported and alcohol intake was measured using 7 day alcohol recall [31] – units of alcohol consumed per week and number of alcohol free days per week were noted.

Dietary intake was measured using the dietary instrument for nutrition education (DINE) questionnaire [32].

Physical activity was assessed using the International Physical Activity Questionnaire [IPAQ] short form [33] and the 6 minute walk test [34].

Health outcomes of interest were explored - fatigue was measured using the multidimensional fatigue inventory (MFI-20) [35] and physical function and quality of life by the EORTC GLQ C30 Quality of Life questionnaire for bowel cancer patients and the EORTC GLQ C29 Quality of Life questionnaire for colorectal cancer patients [36]. Bowel function was assessed by the Low Anterior Resection Syndrome Score (LARS) [37].

Data analysis

Descriptive statistics allowed characterisation of the cohort. Outcome measures were assessed for completeness but no statistical analysis was undertaken given the small sample which was not powered to show definitive results.

Data from proformas completed by the LC were analysed by descriptive statistics (mean ± SD) to estimate completeness of delivery and areas for improvement, and to provide contextual information (including NHS service issues) on patient engagement.

Data from the transcripts were coded by MS and JMcK using a framework approach [38], with an initial framework developed around different aspects of engagement in the study and intervention: recruitment and delivery acceptability, engagement with lifestyle change, facilitators and barriers to lifestyle change, and any issues which would need to be considered if conducting a full RCT. The framework was revised to incorporate additional themes which emerged from the transcripts (for example, concerning PA goals and conflicting advice given by other health professionals).

RESULTS

Recruitment and retention

Over the 7 month recruitment period (01.04.14 to 31.10.14) the number of patients diagnosed and recorded with colorectal cancer was 84 and 22 (26%) were recruited to the study (Figure 1). Of the remainder, 17 were ineligible, unfit or not approached to participate and 45 declined to take part, the most common reason was the extra burden of the study. The median age of non-participants was 74 (range 44 to 90 years) and 49% were male (Table 1). Of the 22 who were recruited, the mean age was 67 years and 77% were male. In total 15 (68%) completed the study (Figure 2). The main reason for drop out at all stages was major ill health.

Table 1 Baseline demographic and clinical characteristics by completion[#]

	Recruited n=22	Completed n=15	Dropped out/lost to follow up n=7
Male Gender	17 (77%)	11 (73%)	6 (86%)
Age: Median (LQ, UQ)	67.0 (60.0, 74.3)	66.0 (60.0, 72.0)	75.0 (64.0, 80.0)
Baseline BMI (kg/m^2): Median (LQ, UQ)	28.3 (25.5, 33.5)	28.6 (26.1, 33.6)	25.8 (24.1, 32.6)
SIMD Category*			
1-3 (most affluent?)	5 (23%)	4 (27%)	1 (14%)
4-7	10 (45%)	7 (46%)	3 (43%)
8-10 (most deprived?)	7 (32%)	4 (27%)	3 (43%)
Smoking Status			
current	2 (9%)	1 (7%)	1 (14%)
ex-smoker	14 (64%)	10 (67%)	4 (57%)
never smoked	6 (27%)	4 (26%)	2 (28%)
Treatments			
Chemotherapy & radiotherapy	3 (14%)	2 (13%)	1 (14%)
Chemotherapy only	6 (27%)	5 (33%)	1 (14%)
No oncology	10 (45%)	8 (53%)	2 (29%)
Palliative care	3 (14%)	0 (0%)	3 (43%)
Cancer staging			
Duke A	3 (14%)	3 (20%)	0 (0%)
Duke B	6 (27%)	3 (20%)	3 (42%)
Duke C	8 (36%)	6 (40%)	2 (29%)
Squamous cell carcinoma	2 (9%)	2 (13%)	0 (0%)
Well differentiated neuroendocrine	1 (5%)	1 (7%)	0 (0%)
Metastases	2 (9%)	0 (0%)	2 (29%)

All results are n (%) unless stated otherwise

*SIMD Scottish Index of Multiple Deprivation

Programme Implementation

The median time in phase 1 (pre-habilitation) was 15 days. The median time in phase 2 was 36.5 days and phase 3 was 102 days but was frequently extended by clinical problems due to health status post-surgery, treatment responses and pre-existing co-morbidities. Table 2 illustrates the significant and varied challenges experienced by individual participants during the recovery phase. Many patients did not have sufficient time in phase 3 (prior to project end) to enable secondary outcomes to be reliably assessed.

Table 2 Summary of participants' clinical progress during the TreatWELL study

Participant completed study n= 15 Dropped out n=7

1	Biopsy showed advanced disease after patient had undergone baseline measures and the phase 1 LC intervention visit. Patient excluded from further study measures.
2	Surgery as planned but poor postoperative recovery and discharged to a continuing care unit. Intravenous (IV) chemotherapy started after discharge home followed by oral chemotherapy and radiotherapy. Waiting for stoma reversal. All phases of study completed.
3	Surgery as planned. Slow recovery post-surgery and on parenteral nutrition. No adjuvant therapies required. Discharged home with carers twice a day, walking with a Zimmer frame. May have further surgery and did not progress beyond phase 2 in study. Seen at peripheral hospital.
4	Surgery as planned. No adjuvant therapies required. Became worried about recurrence after discharge and had to have psychological support. Hip pain re-started in phase 3. Lung metastases and heart failure diagnosed. Dropped out during phase 3. Patient died.
5	Surgery as planned. No adjuvant therapies required. All study phases completed.
6	Short phase 1. Emergency surgery to de-function bowel (stoma formation). Successful chemotherapy and radiotherapy before main surgery. Phases 2 and 3 switched round for this participant. All study phases completed.
7	Surgery as planned then admission to high dependency unit post-operatively. Discharged but re-admitted for further surgery and stoma formation. Chemotherapy given. All study phases completed.
8	Surgery performed. Further surgery performed for removal of residual tumour. Stoma reversed. No adjuvant therapies required. All study phases completed.
9	Biopsy showed advanced disease after patient had undergone baseline measures. Patient not going ahead for surgery and excluded from further study measures.
10	Surgery as planned and chemotherapy. Admitted with diabetic ketoacidosis but diabetes since resolved. Slow recovery. Phase 1 delivered day before surgery Phase 2 and 3 of study completed.
11	Short phase 1. Surgery performed. No adjuvant therapies required.. Completed phase 2 and 3 of the study.
12	Phase 1 delivered day before surgery. Surgery performed. Chemotherapy commenced early due to cancellation in clinic and completed. Phase 2 completed. Wife has health issues which prevented him completing phase 3.
13	Surgery as planned, No adjuvant therapies required. All phases of study completed. Home visits.
14	Surgery as planned and chemotherapy started after surgery. All study phases completed. Seen at peripheral hospital.
15	Surgery as planned and no chemotherapy required. All phases of study completed (short phase 1).Home visits.
16	Surgery as planned, No adjuvant therapies required. All phases of study completed. Home visits.

17	Surgery as planned. Oral chemotherapy after surgery. All phases of study completed.
18	For de-functioning stoma and pre-surgery radiotherapy and chemotherapy. Surgery performed. Lost to follow up as still requiring intensive treatment at study end (phase 1 and 2 only).
19	Surgery as planned but re-admitted. Slow recovery from surgery with significant complications. Phase1, 2 and 3. Dropped out of study during phase 3 as felt back to normal and did not require further support.
20	No phase 1 undertaken. Surgery as planned, long post-operative recovery. No adjuvant therapies required. Phase 2 and 3 of study completed.
21	Surgery performed. No adjuvant therapies required. All phases of study completed. Home visits.
22	Phase 1 delivered day before surgery. Surgery performed. Chemotherapy required. Phases 2 and 3 of study completed.

Total median intervention delivery by lifestyle counsellors was 5 hrs 29 mins. LCs reported that patient engagement was high, with 93-100% being at least "fairly engaged" at all stages. Similarly the LCs reported that participants were receptive and interested in the information being delivered.

LCs rated participants as at least "fairly motivated" to improve diet and physical activity levels. During the immediate recovery stage (phase 2) LCs were most likely to report goal setting for diet and PA as "neither easy nor difficult" (73% and 64% for diet and PA respectively). At the phase 3a time point, LCs rated the ease of goal setting more favourably, with 46% of consultations described as "easy" to set dietary goals and 82% for PA.

Achieved Measurements

Baseline measures were completed on all participants, except in four cases, where the 6 minute walk test had to be excluded due to lack of space in the participant's home. Only 6 out of 33 participants were seen at the end of phase 1 due to the difficulty in fitting in visits prior to surgery. All participants remaining in the study were seen at the end of phase 2, but it was not possible to carry out all anthropometric measurements and walking tests at this point. Walking tests were not possible at the end of phase 3. Questionnaire data were generally well completed however some participants were reluctant to answer sexual function questions (LARS questionnaire) in all phases.

Factors affecting protocol adherence

The LCs reported that they were able to cover most of the intervention components during phase 1 (78% delivery), 3a (73% delivery) and 3b (90% delivery). However, during the post-surgical phase (phase 2), LCs reported difficulties with access to patients. Lifestyle counselling was reported as most challenging during visits 1 (first contact) and 2 (immediately post-surgery). Delivery became more comfortable towards the end, with LCs reporting 70% of the final sessions as "fairly easy" (compared with 39% in Phase 1 and 46% in Phase 2).

The major challenges of intervention delivery reported by the LCs were:

- The short time between diagnosis and surgery

- Participants identifying time to fit in the baseline and intervention visits in addition to diagnostic and treatment preparation schedules
- Seeing patients in phase 2 (short period)
- Difficulties identifying the transition from end of phase 2 and start of phase 3
- Poor clinical progress (some patients were readmitted)
- Due to complications a longer treatment period was required which extended phase 3 beyond the project life
- Mixed messages from NHS staff and TreatWELL LCs

Participants views on acceptability

Of 20 participants who completed phase 2, 14 were invited for interview, 3 declined and 11 participated (7 men and 4 women), with a mean age of 66 ± 6 (range 57 to 75) years. Interviewees were from a range of areas of deprivation.

Most participants recalled that they had been recruited around the time of their diagnosis. For some, this timing appeared to have facilitated participation, as the study offered a potentially beneficial experience on which to focus, taking their mind off their diagnosis and concerns for the future. Several were reassured by the endorsement of colorectal consultants. Generally, the amount of contact, and the balance between visits and telephone calls, appeared acceptable, and the provision of home visits was particularly appreciated. Some appeared a little apprehensive about the prospect of 'going it alone' at the end of the study but they recognised that its end signalled another milestone in their recovery. Participants spoke positively of LCs and felt that LCs had been able to move them gently into doing things they might have been reluctant to do. Some hinted that they had relied on the counsellor for wider emotional support.

The PA advice appeared to have been particularly salient, with most participants being able to describe their PA goals and targets. Pedometers were felt to have been very helpful. Some described having become so fixed on their PA goals that they "over-did things", but most felt that the advice had encouraged them to be more active and to "push" themselves more than they might otherwise have done. Participants generally felt that they had managed to take on board the diet advice, although some had struggled with cutting out 'treats'.

A number of facilitators and barriers to engagement were identified. Prior enjoyment of walking and previous experience of weight loss programmes were both beneficial, as were supportive family members who encouraged adherence to healthy eating and sometimes participated in activity along with the participant. Receiving a diagnosis of cancer was a major motivator for adherence. Participants were determined to overcome their diagnosis and quickly regain their health, not least for significant others. Similarly, participants were motivated to make changes in order to put themselves in the best condition for surgery and to optimise their recovery. One woman was motivated to maintain a healthy weight during her stay in hospital by witnessing fellow patients who were overweight struggling with their mobility. Monitoring progress especially with regard to levels of PA also provided motivation and some enjoyment for participants.

A main factor which negatively affected adherence to the intervention was participants' physical health. Some participants felt too unwell to increase PA, although this was alleviated for some by building

strength gradually, whilst others described comorbidities hampering their attempts to be physically active.

Some clinical staff were reported to have advised participants to gain weight by eating whatever they liked and by not discouraging unhealthier foods, in direct contrast to TreatWELL. This inconsistency caused confusion, and participants reported following the advice of clinical staff. Participants also highlighted that NHS staff had little awareness of TreatWELL and appeared to provide little encouragement. More generally, it was noted that nursing staff did not encourage patients to get up and move on the ward.

Secondary Outcomes

There was no change in smoking habits – one of the two smokers at baseline was lost to follow-up and the other smoker continued to smoke. The number of participants who reported consuming alcohol decreased between baseline and end of phase 3 although in some individuals intake increased. PA data shows a positive trend towards increased activity overall. For the 15 who completed the study, minutes of physical activity nearly doubled from a median of 480 (IQ range 240 – 720) per week to 840 (IQ range 330 to 1260). This was largely due to an increase in leisure time activities, but, a decrease in active time at work (few participants continued to work during the study period). Dietary data indicated no increase in total fat score but a desirable increase in fibre score. Quality of Life data indicated some increase in global health function but also increases in anxiety.

The majority of participants had excess weight (77%) and 40% were obese at baseline (Table 1). None were underweight. At the end of phase 2, body weight had decreased as expected in the post-surgical period. Despite this weight loss, no underweight individuals were detected at the end of phase 3 and the proportion with excess weight remained. The 6 minute walk test indicated no decrease in functional ability by the end of phase 3.

It should be noted however, that all secondary outcome results were obtained principally to test ability to undertake measures and are not powered to detect differences.

DISCUSSION

Whilst it is recognised that pre-surgical (prehab) lifestyle intervention may have significant impact on improving health outcomes in the early months following a diagnosis of colorectal cancer there is little evidence of multi-component intervention RCTs to support investment in this area. This study illustrates the complexities of delivering and evaluating such interventions and highlights issues that need to be addressed prior to progressing further work. The main findings show that it is difficult to recruit at diagnosis because of the multitude of investigations taking place, the staff's perceptions of frailty and age (although all participants were deemed fit for surgery) and the relatively short period available for recruitment, baseline data collection and intervention delivery before surgery. It is notable that a high proportion of participants were male (77%) and whilst national data reports [39] that more men are diagnosed with colorectal cancer compared to women (54% versus 46%), the proportion in this study is higher than anticipated. The reason for this is not clear but does indicate the need to explore this in future work. Phase 2 was predictably short for most patients, but longer in those who had previous illness or had developed post-surgical complications. It should be noted that because patients were recruited at diagnosis, the extent of the disease (i.e. stage) was unknown and complications were unpredictable. Many participants spent insufficient time in phase 3 (prior to study end) for the impact of the

intervention to be assessed, highlighting the need for a longer study duration for final outcome measurements. The clinical pathways of participants were unpredicted and impacted on study retention. The hardest challenge in delivery was when to introduce the next phase of the intervention (phase 2 to phase 3) because many participants had complex journeys through treatment. These findings highlight that compliance with a strict RCT protocol for this type of intervention is likely to be difficult. Outcome measures were largely acceptable, although consideration should be given to whether the more sensitive questions on quality of life are required. Participant views suggest the intervention was largely acceptable, and that the focus on physical activity was appropriate. The high number of patients with excess body weight at study recruitment (and exit) is of concern and a future trial encompassing weight loss is likely to need long term support and follow up.

This study (to the best of our knowledge) is the first to have offered a comprehensive lifestyle intervention at diagnosis with support before, during and after treatment in patients with colorectal cancer. Although the study is small and was undertaken in a single NHS health board, the results have highlighted a wide range of issues that would need to be addressed in a full trial of a multi-component intervention. The lack of randomisation means that it is not possible to assess whether uptake to a randomised trial with control condition would be similar.

Moug et al [40] have recently reviewed 14 randomised controlled trials in this patient group and concluded that lifestyle interventions are feasible in patients with CRC. However, it is notable that there were no RCTs of tobacco and alcohol. In general, they reported variable recruitment rates but good adherence and retention (as is the case in our own study). Ravasco et al [13] have demonstrated positive outcomes in CRC patients referred for radiotherapy (irrespective of other therapies provided) after dietary counselling. However, other trials of diet and lifestyle have been focussed on patients after the end of treatment [14, 41, 42]. The challenges to conducting a trial in this patient group are similar to those described by Hubbard et al [43] in feasibility work of a pragmatic RCT for a group based rehabilitation programme for CRC survivors which reported a high likelihood of recruitment bias, potential of sub-optimal completion of outcome data, missing data and poor intervention adherence.

The current intervention approach is ambitious, but could be refined for testing in an RCT if all visits can be linked more closely with clinical appointments, measurement visits are reduced and if the clinical team were encouraged to help support lifestyle changes. Fundamentally interventions being tested should be scalable, durable and cost effective [44]. Whilst there is much practical guidance on diet and lifestyle for cancer survivors [45, 46] and interventions which have been demonstrated to be safe and feasible there remains a need for studies that can demonstrate the impact of lifestyle intervention on disease outcomes. Research in this area requires multilevel approaches with full support from health service staff (both in recruitment and support for lifestyle action), intervention staff for the delivery of tailored, personalised approaches and patient interest and advocacy.

CONCLUSIONS

To make this intervention feasible for testing as a full RCT, further research is required on a) recruitment optimization b) appropriate assessment tools c) protocols for phase 2 and 3 which can build in flexibility and d) ways for NHS staff to facilitate the programme.

Figure legend

Figure 1 TreatWELL recruitment CONSORT flowchart

Figure 2 TreatWELL study progression CONSORT flowchart

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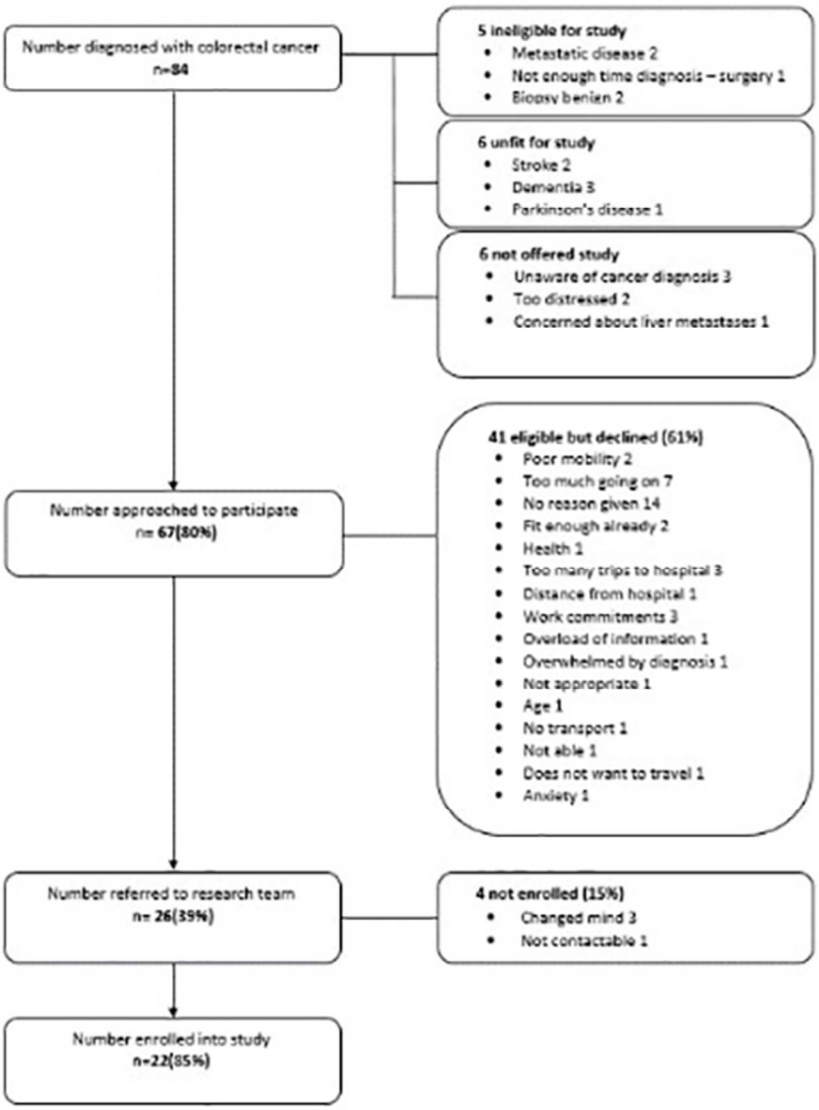

Figure 1 TreatWELL recruitment CONSORT flowchart

46x64mm (300 x 300 DPI)

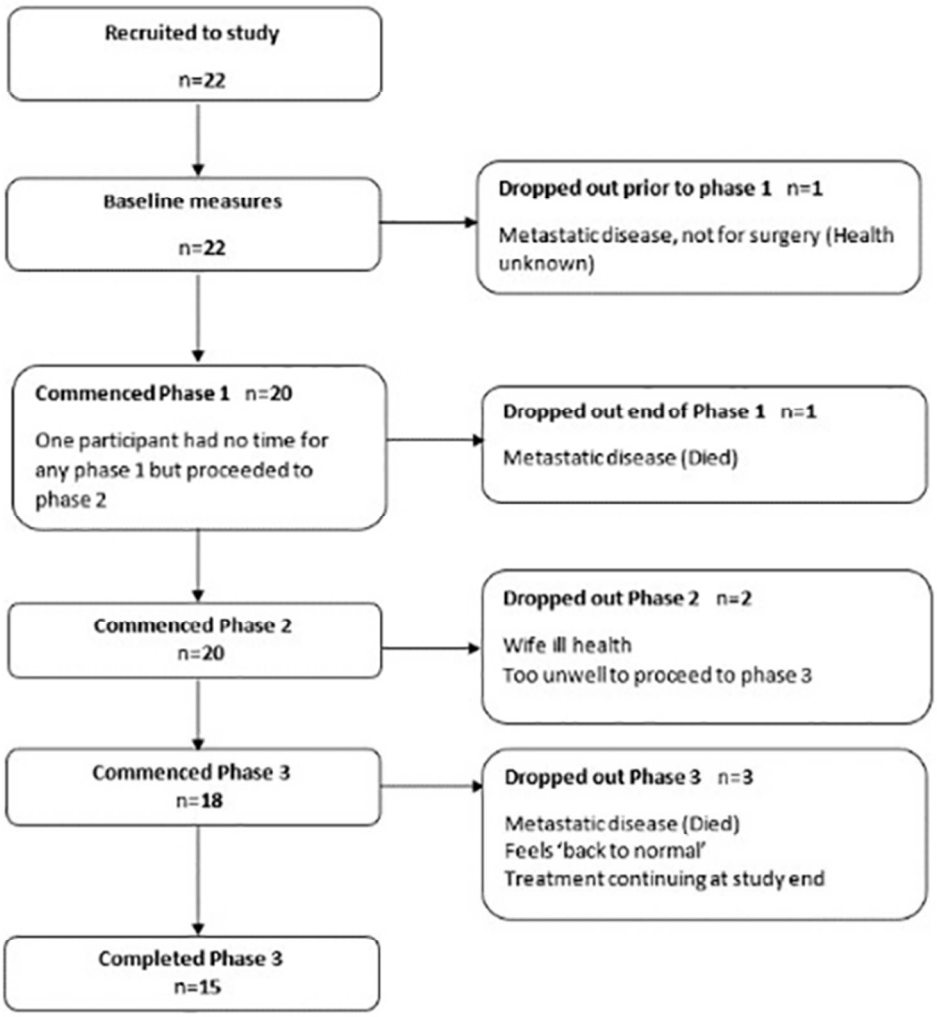

Figure 2 TreatWELL study progression CONSORT flowchart

55x59mm (300 x 300 DPI)

Appendix 1 TreatWELL intervention delivery plan and resources

Phase 1 Prehabilitation

a) Delivery mode:

Face to face study consultation visit 1 (1 hour) (hospital/research centre). All participants were encouraged to bring a support friend/family member

Consultation Focus:

Getting fit for surgery

- Education and endorsement on smoking, alcohol, physical activity, fruit and vegetables (FAV))

Resources:

- Fast track smoking cessation card
- Leaflet *How to stop smoking and stay stopped* booklet
- AUDIT alcohol assessment
- NHS Scotland alcohol booklet: *Making a Change*
- Macmillan DVD and booklet on physical activity
- DoH physical activity guidelines
- Pedometer

Behaviour change techniques

- Motivational Interviewing questions
- Goal setting for 2 health behaviours (smoking, alcohol, physical activity, diet, FAV)
- Implementation Intentions (smoking, alcohol, physical activity, FAV)
- Self-monitoring (activity diary)

AND Telephone home calls (1 to 2) 10-15 minutes (home)

Phase 2 Surgical Recovery

a) Delivery mode:

Brief face to face support meeting (10- 15 min; in hospital ward)

Consultation Focus:

Recovery and continuing support

- Consistent with Enhanced Recovery After Surgery protocol (ERAS)
- Support about relevant post-operative physical activity
- Education and endorsement about diet (regular meals, sugary drinks, FAV)
- Advice offered on smoking and alcohol as appropriate

Resources:

- Bowel Cancer UK booklets: *Eating and Drinking During Treatment, Fibre after Bowel Cancer* (as appropriate),
- Phase 2 activity diary

Behaviour change techniques

Phase 2 (early phase 3)

b) Delivery mode:

Brief telephone/ward contacts 10-15 minutes

Consultation Focus:

Recovery and continuing support

- 1st visit/call Supportive for managing goals
- 2nd visit/call Responding to queries about diet, physical activity, alcohol, smoking

Phase-3 Post surgical/adjuvant therapy/ recovery

a) Delivery mode:

Face to face consultation study visit 2 (1 hour; hospital/ research centre)

Participants not on chemotherapy Visit takes place start of phase 3	**Participants on Chemotherapy** Visit takes place half way through chemotherapy
Consultation Focus: A new start • Diet, Keep active (walk and talk), • Management of weight **Resources**: • Eatwell plate • 7 day food and drink diary • Booklet: *Thinking about becoming more active?* • 12 week activity diary • Resistance bands • NHS Tayside information *Helping you manage your weight* • Information about personalised weight management • Bowel Cancer UK booklet: *Losing Weight Safely* • Weight awareness plan **Behaviour Change techniques** • Goal setting for two health behaviours physical activity, smoking, alcohol, diet • Implementation intentions • Self-monitoring (body weight log)	**Consultation Focus** A new start • Diet, Keep active (walk and talk), • Introduce weight management concepts **Resources**: • Eatwell plate • 7 day food and drink diary • Booklet: *Thinking about becoming more active?* • 12 week activity diary • Resistance bands **Behaviour Change techniques** • Goal setting for two health behaviours physical activity, smoking, alcohol, diet • Implementation intentions • Self-monitoring (body weight log)

Face to face consultation study visit 3 (1 hour; hospital/research centre)

Participants with no chemotherapy Scheduled 4 weeks post consultation study visit 2	**Chemotherapy** Visit takes place at end of chemotherapy
Consultation Focus: • "Future planning" • Education and endorsement on healthy eating, • Reinforce physical activity advice **Resources**: • *TREATWELL Getting active and eating well after Bowel Cancer treatment* • Calories and alcohol information **Behaviour Change techniques**	**Consultation Focus**: • "Future planning" • Management of weight • Education and endorsement on healthy eating • Reinforce physical activity advice **Resources**: • NHS Tayside information *Helping you manage your weight* • Information about personalised weight management • Bowel Cancer UK booklet: *Losing Weight Safely* • Weight awareness plan • *TREATWELL Getting active and eating well after Bowel Cancer treatment* • Calories and alcohol information **Behaviour Change techniques**

And up to 8 Brief telephone calls 10-15 minutes at home

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5, 6
	2b	Specific objectives or research questions for pilot trial	6
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6-9
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	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	8, 9
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	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	6
	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	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
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	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	8, 9
Results			
Participant flow (a diagram is strongly recommended)	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	10, Figs 1 & 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	10, 11, Figs 1 & 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	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	10
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	12
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	12-14
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
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	2,14
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	15
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	15
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	15
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3
	26	Ethical approval or approval by research review committee, confirmed with reference number	3

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.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

A feasibility study to assess the delivery of a lifestyle intervention (TreatWELL) for colorectal cancer patients undergoing potentially curative treatment.

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Secondary Subject Heading:	Patient-centred medicine
Keywords:	Prehabilitation, Lifestyle intervention, Colorectal cancer

A FEASIBILITY STUDY TO ASSESS THE DELIVERY OF A LIFESTYLE INTERVENTION (TREATWELL) FOR COLORECTAL CANCER PATIENTS UNDERGOING POTENTIALLY CURATIVE TREATMENT.

Authors

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ABSTRACT

Objectives To assess the feasibility of delivering and evaluating a lifestyle programme for colorectal cancer patients undergoing potentially curative treatments.

Study design Non-randomised feasibility trial

Setting NHS Tayside

Participants Adults with stage I - III colorectal cancer

Intervention The programme targeted smoking, alcohol, physical activity, diet and weight management. It was delivered in 3 face-to-face counselling sessions (plus 9 phone calls) by lifestyle coaches over three phases (1 - pre-surgery, 2 - surgical recovery and 3 - post treatment recovery).

Primary outcome Feasibility measures (recruitment, retention, programme implementation, achieved measures, fidelity, factors affecting protocol adherence and acceptability).

Secondary outcomes Measured changes in body weight, waist circumference, walking and self – reported physical activity, diet, smoking and alcohol intake, fatigue, bowel function and Quality of Life (QoL).

Results Of 84 patients diagnosed, 22 (26%) were recruited and 15 (18%) completed the study. Median time for intervention delivery was 5.5 hours. Coaches reported covering most (>70%) of the intervention components but had difficulties during phase 2. Evaluation measures (except walk test) were achieved by all participants at baseline, and most (<90%) at end of phase 2 and phase 3, but <20% at end of phase 1. Protocol challenges included limited time between diagnosis and surgery and the presence of co-morbidities. The intervention was rated highly by participants but limited support from NHS staff was noted. The majority of participants (77%) had a BMI >25kg/m^2 and none were underweight. Physical activity data showed a positive trend towards increased activity overall but no other changes in secondary outcomes were detected.

Conclusions To make this intervention feasible for testing as a full trial, further research is required on a) recruitment optimisation b) appropriate assessment tools c) protocols for phase 2 and 3 which can build in flexibility and d) ways for NHS staff to facilitate the program.

Trial registration number ISRCTN 52345929

STRENGTHS AND LIMITATIONS

- This feasibility study is the first to have offered a comprehensive lifestyle intervention programme at diagnosis with support before, during and after treatment in patients with colorectal cancer.
- The study highlights the wide range of variables that need to be considered in designing a future randomised controlled trial (including recruitment and support from NHS staff, complexities of patient health status and time required for permissions, assessment and interventions).
- The lack of randomisation means it is not possible to estimate uptake to a randomised controlled trial.
- The work was undertaken in a single NHS health board and may not be representative of other treatment centres.

COMPETING INTEREST STATEMENT

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work other than the Chief Scientist Office who funded the award, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

ETHICS, CONSENTS AND PERMISSIONS

Ethical approval was provided by the East of Scotland Research Ethics Service, REC reference no. 13/ES/0153. All participants provided written, informed consent.

FUNDING

Funding for this study was provided by the Chief Scientist Office (CZH/4/939). The funders played no part in the design, execution or decision to publish this research.

AUTHORS' CONTRIBUTION

All authors have made substantial contributions to the study conception and design, and the development and editing of the manuscript. MM led initial study design and development, assisted with data collection, carried out the analyses and drafted the initial draft manuscript; RJCS had the initial concept and led initial study design and development; RO'C led the fidelity assessments (development and analyses) and provided guidance on project progression; MW had the initial concept and led initial study design and development; AC contributed to study design; JS carried out the day to day management of the study and led the data collection; JR contributed to study design; MS and JMcK led on qualitative assessments (development and analyses); ASA had the initial concept and led initial study design and development, contributed to data analyses and had oversight of the study.

All authors have read, edited and approved the manuscript for publication.

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We would like to thank the participants of this study, lifestyle coaches Catherine Savage and Carol Baird and the study administrator Jill Hampton who arranged the interviews and FGDs.

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DATA SHARING

Technical appendix, statistical code, and dataset available from the authors on request.

INTRODUCTION

Colorectal cancer (CRC) survival has improved in the last decade due to earlier diagnosis and new treatments but, in Scotland, survivors still have notable excess mortality within the ***first year post diagnosis*** compared to other European countries [1]. Survivors also have a high rate of pre-existing co-morbidities and treatment related symptoms. The latter are experienced by 15% undergoing colonic surgery, 33% with rectal surgery, 50% of those with chemo-radiation therapy and 66% of patients undergoing short course radiotherapy. These symptoms include fatigue, physical discomfort and bowel function problems [2].

In people diagnosed with cancer it is recognised that smoking cessation, improved physical activity and diet have the potential to impact on treatment outcomes and cancer recurrence. A number of studies have reported that higher levels of physical activity are associated with better physical functioning [3] and reduced fatigue [4] although further work is needed in this area [5]. Follow up studies report better disease free, recurrence free and overall survival in people who are more physically active [6, 7]. Intervention trials have shown that higher levels of physical activity initiated at pre-habilitation (pre surgery), post-surgery, during and after adjuvant therapies (rehabilitation) [8-10] are associated with improved cardiorespiratory fitness, muscular strength, physical functioning, quality of life, and reduced psychosocial distress.

There is growing evidence for the impact of diet on CRC cancer outcomes [11]. A large observational study has reported that a higher level of a Western dietary intake (compared to a lower level of Westernisation) resulted in lower disease-free and overall survival rates [12]. At intervention level, a trial of dietary counselling delivered during treatment [13] showed that nutrition improvements were associated with reduced treatment related co-morbidity (radiotherapy toxicity) at ***3 months*** and after a mean follow up of 6 years. Three post-treatment exploratory trials [14-16] of combined lifestyle interventions have reported improved dietary behaviour, reduced fatigue, improved exercise tolerance, functional capacity and quality of life.

There is some evidence to support lifestyle interventions in the pre-surgical and post- treatment periods, but no trial has yet evaluated an intervention covering the full patient journey. Patients report confusion about appropriate lifestyle behaviours because they have received conflicting advice at different treatment stages and rarely receive personalised support in the period after treatments end and during return to normal health [17]. It has been noted that relatively few CRC patients stop smoking after diagnosis (13.7% pre-diagnosis to 9% 5 months later) [18]. Current data suggest that, in CRC patients, physical activity levels drop significantly by 6 months post-diagnosis [19]. This may reflect lack of consistent guidance from clinicians, and patient confusion over the merits of rest versus activity [20]. Similarly, for diet, misconceptions exist over body weight gain (or loss) and understanding of appropriate food selection.

There are a number of behavioural frameworks that could support lifestyle change from the start of care such as the concept of the “teachable moment” [21]. Cancer care clinicians, starting at diagnosis and throughout the cancer pathway, can be powerful advocates to help patients understand the importance of a healthy lifestyle and they have expressed interest in providing guidance [22]. Patients consider information obtained from cancer specialists to be of the best quality [20]. Despite major concerns over their diagnosis many patients request advice on what might be done to prepare for surgery and there is a need for clinicians to identify an effective programme with the potential to improve health in the first year after diagnosis. Increasingly, asymptomatic patients are diagnosed via the national bowel screening programme which means that this patient group is less frail than those

diagnosed late and have considerable potential to initiate lifestyle change. Opportunities in the "pre-habilitation" period have been highlighted in cancer strategy documents [23] but little is known about likely uptake of interventions.

This study aimed to assess the practical aspects of delivering and evaluating a lifestyle intervention programme (TreatWELL) for CRC patients undergoing potentially curative treatments in order to inform the feasibility of undertaking a randomised controlled trial (RCT) to assess the clinical and cost-effectiveness of this intervention at one year after diagnosis.

Specific objectives were to assess recruitment and retention to assist in the design of a future RCT, assess the feasibility of data collection procedures, ease of programme implementation, patient acceptability, fidelity and factors influencing adherence to the intervention.

METHODS

Study design and setting

This study was a single arm, two-centre feasibility study of the TreatWELL intervention programme carried out in tertiary level teaching hospitals in Tayside, UK.

Sample size

We aimed to recruit 34 participants in order to be able to assess feasibility objectives and to provide data to inform the sample size required to show significant differences in health outcome variables in a fully powered RCT. These numbers were based on a pragmatic assessment of patient numbers, eligibility and participation based on a previous study undertaken with the same patient group (at post-treatment stage) in the same geographic area [15].

Eligibility

Eligible patients were adults aged >18 years , capable of giving informed consent, considered to have stage I to III colorectal cancer, eligible for potentially curative treatment (had to be fit for major surgery). It should be noted that participants were recruited before CT Scans and eligibility was based on clinical examination. Patients who had severe cognitive impairment, emergency surgery or pre-operative neo-adjuvant therapy were excluded from the study.

Recruitment

Eligible patients were introduced to the study by a clinical nurse specialist (CNS) after discussing treatment and care plans following a cancer diagnosis. At this meeting the CNS introduced the study and endorsed its importance for helping to achieve lifestyle change in the pre-surgical period. Interested patients were provided with a participant information sheet, an invitation and endorsement letter from the lead CRC clinician for Tayside and a pre-paid opt-in reply slip which they could return to the research team. A research nurse (RN) then contacted patients, who had either provided their contact details to the CNS or returned the pre-paid reply slip, to discuss the study in detail and (if appropriate) make an appointment to obtain written informed consent and take baseline measurements. This appointment was held at the referring hospital or the participant's home if a hospital location was reported as a barrier to participation.

Intervention

The TreatWELL intervention programme aimed to facilitate collaboratively agreed behaviour changes towards achieving and maintaining smoking cessation, increased physical activity (to at least 150 minutes moderate intensity activity per week), caloric intake appropriate to weight status and a nutrient dense diet. All goals were consistent with the American Cancer Society and World Cancer

Research Fund guidance for cancer survivors [24, 25]. The behavioural approaches were informed by two main theoretical frameworks: self-regulatory theory [26] and the health action process approach [27].

Following baseline measures consented patients' contact details were passed to a Lifestyle Coach (LC) who then commenced the TreatWELL personalised intervention. The LCs had a nursing background, experience with cancer patient management and underwent a 3 day bespoke training programme covering smoking cessation, increasing moderate physical activity, brief interventions on alcohol and weight management (post-surgical and post treatment). The intervention was delivered via three face-to-face contacts (one per intervention phase and a minimum of 9 phone calls) supported by written literature and a range of behavioural techniques.

- Phase 1 Pre-habitation to start within 3-10 days of diagnosis to surgery
- Phase 2 Surgical recovery to start 1 day post-op and aim to complete within 21 days
- Phase 3 Post-surgical / adjuvant therapy recovery to start 21 days post-op for 25 weeks

The total intervention period comprised 31 weeks although duration was flexible as it was based on the individual's treatment regimen. The delivery mode, consultation focus, resources and behaviour change techniques used in each phase are presented in Appendix 1. Decisions about phase completion (e.g. defining the end of post-surgical recovery) and progression was agreed in conjunction with the CNS. In summary, each phase of the programme comprised verbal educational approaches with written resources (e.g. booklets, resistance bands) and the use of behavioural techniques. Importantly, personalised, specific action goals were identified with a focus on two health behaviours that were selected as a priority for that individual (e.g. smoking, physical activity). All participants were invited to engage a support person (e.g. spouse) to assist in their adherence with the programme. It should be noted that the protocol for phase 3 varied according to whether chemo therapy use. For patients with no adjuvant therapy, the progression to addressing body weight issues (over, under weight and weight loss) was addressed at the start of this phase. For participants undergoing chemotherapy the focus on diet and weight management was delayed to avoid any confusion which might arise with dietary issues related to treatment side effects (e.g. nausea).

Participants were encouraged to develop personalised action and coping plans. Activities (e.g. brisk walking) were demonstrated and tried by participants. Access to an equipment tool kit (pedometers, resistance bands and DVDs) was also offered. Emphasis was placed on self-monitoring and goal setting, e.g. physical activity through pedometers, with weekly feedback in the first week of each phase. In phase 2, participants were encouraged to commence activity in accordance with ability, their post-op condition and guidance from their health care team. In Phase 3, the participant's Phase 1 plan was repeated and expanded to include an emphasis on core strength, mobility and functional ability, with a strict protocol for referral to a physiotherapist if there were any safety concerns.

In phase 1, advice for participants not at risk of malnutrition (BMI>20kg/m^2) focused on avoiding weight gain and increasing nutrient quality of their diet in line with the Department of Health Eatwell guide [28]. Participants were also advised about decreasing alcohol intake, as appropriate. No energy prescription was set in phase 1. In phase 2 and initially in phase 3, nutrition advice focused on symptom management (e.g. anorexia, vomiting and bowel problems) and worked towards achieving a nutrient dense diet. In the later stage of phase 3, all participants (BMI>20kg/m^2) were given personalised guidance on a nutrient dense diet and avoidance of excess weight gain. Participants with a BMI>25kg/m^2 were advised on avoidance of weight gain and modest weight reduction (>5% weight loss) using a personalised energy prescription goal. Communications emphasised the concept of building resilience through the combined approach of increasing muscle mass (through physical

activity) and decreasing excess body fat (through caloric reduction). The importance of regular self-weighing was stressed and feedback provided at each telephone consultation.

Informed by behaviour change techniques used in previous interventions [29] and the behaviour change wheel [30], a range of evidence-based behavioural techniques were employed to motivate and support lifestyle change. These included motivational interviewing, formation of specific implementation intentions, self-monitoring, personalised action and coping plans, feedback and re-enforcement.

Measurements

The research nurses prospectively collected details on socio-demographic background, clinical information (including tumour stage and site), type of surgery, stoma status, medications and details of adjuvant treatments.

Primary Outcome Measures

Recruitment and retention were assessed from research nurse records. Information on reasons why patients were ineligible or choose not to participate were recorded with patient consent.

Programme implementation (by LCs) was estimated from a structured pro-forma completed after every patient contact which recorded actual values or scaled ratings on:

- Intervention start time (days after diagnosis)
- Total contact time
- Ease or difficulty of implementing the session
- Perceived fidelity to the intervention content
- Extent of patient engagement, receptivity and motivation

Achieved measurements (by RNs) were recorded at baseline and the end of each phase of the study.

Participants' views on acceptability of the intervention and factors influencing adherence were explored in in-depth qualitative interviews conducted by MS and JMcK. Interviews were scheduled for around 45-60 minutes and were conducted either face to face or by telephone. Interviews were digitally recorded with participants' consent, and transcribed verbatim for analysis. The original intention was to interview a random sample of one in three participants at the end of phase 2 and another at the end of phase 3. However, because of the low number of participants everyone was invited to take part in an interview towards the end of their journey through the intervention programme.

Secondary outcome measures

Anthropometric measures were taken as follows:

- Body weight measured with the participant wearing indoor clothing and no shoes, using a calibrated Seca 877 digital scale.
- Height measured with a Seca Leicester portable stadiometer.
- Body mass index (BMI) was calculated – weight (kg)/height (m)^2.
- Waist circumference measured with a Seca 201 measuring tape, with the participant in the standing position and the tape positioned midway between the lateral lower rib margin and the iliac crest. If these landmarks could not be identified, the measurement was taken at the level of the umbilicus. Two measurements were taken post-exhalation and the mean recorded.

Smoking status was self-reported and alcohol intake was measured using 7 day alcohol recall [31] – units of alcohol consumed per week and number of alcohol free days per week were noted.

Dietary intake was measured using the dietary instrument for nutrition education (DINE) questionnaire [32].

Physical activity was assessed using the International Physical Activity Questionnaire [IPAQ] short form [33] and the 6 minute walk test [34].

Health outcomes of interest were explored - fatigue was measured using the multidimensional fatigue inventory (MFI-20) [35] and physical function and quality of life by the EORTC GLQ C30 Quality of Life questionnaire for bowel cancer patients and the EORTC GLQ C29 Quality of Life questionnaire for colorectal cancer patients [36]. Bowel function was assessed by the Low Anterior Resection Syndrome Score (LARS) [37].

Data analysis

Descriptive statistics allowed characterisation of the cohort. Outcome measures were assessed for completeness but no statistical analysis was undertaken given the small sample which was not powered to show definitive results.

Data from proformas completed by the LC were analysed by descriptive statistics (mean ± SD) to estimate completeness of delivery and areas for improvement, and to provide contextual information (including NHS service issues) on patient engagement.

Data from the transcripts were coded by MS and JMcK using a framework approach [38], with an initial framework developed around different aspects of engagement in the study and intervention: recruitment and delivery acceptability, engagement with lifestyle change, facilitators and barriers to lifestyle change, and any issues which would need to be considered if conducting a full RCT. The framework was revised to incorporate additional themes which emerged from the transcripts (for example, concerning PA goals and conflicting advice given by other health professionals).

Patient and Public Involvement

The Chair of Tayside Cancer Patient and Public Involvement Group provided guidance on project development and progression. The group also identified a potential patient rep who subsequently assisted in reading and commenting on study design, communication materials and specific questions. Guidance was requested from the patient rep on sensitive communications regarding body weight and introducing the topic. Patients were not involved in study recruitment.

We have no plans to disseminate the results of this feasibility work to participants.

RESULTS

Recruitment and retention

Over the 7 month recruitment period (01.04.14 to 31.10.14) the number of patients diagnosed and recorded with colorectal cancer was 84 and 22 (26%) were recruited to the study (Figure 1). Of the remainder, 17 were ineligible, unfit or not approached to participate and 45 declined to take part, the most common reason was the extra burden of the study. It should be noted that because of the short window for intervention, some participants were recruited before CT Scans were complete. In one case, lung metastases were diagnosed after CT staging. Surgery was still undertaken for this patient on the clinical basis that it had the potential to improve survivorship.

The median age of non-participants was 74 (range 44 to 90 years) and 49% were male (Table 1). Of the 22 who were recruited, the mean age was 67 years and 77% were male. Baseline data on Body Mass Index (BMI) and key health behaviours (smoking, physical activity, alcohol and diet score) indicate significant potential for health gain.

In total 15 (68%) completed the study (Figure 2). The main reason for drop out at all stages was major ill health.

Table 1 Baseline demographic and clinical characteristics by completion[#]

	Recruited n=22	Completed n=15	Dropped out/lost to follow up n=7
Male Gender	17 (77%)	11 (73%)	6 (86%)
Age: Median (LQ, UQ)	67.0 (60.0, 74.3)	66.0 (60.0, 72.0)	75.0 (64.0, 80.0)
Baseline BMI (kg/m^2): Median (LQ, UQ)	28.3 (25.5, 33.5)	28.6 (26.1, 33.6)	25.8 (24.1, 32.6)
SIMD Category[#]			
1-3 (most affluent?)	5 (23%)	4 (27%)	1 (14%)
4-7	10 (45%)	7 (46%)	3 (43%)
8-10 (most deprived?)	7 (32%)	4 (27%)	3 (43%)
Smoking Status			
current	2 (9%)	1 (7%)	1 (14%)
ex-smoker	14 (64%)	10 (67%)	4 (57%)
never smoked	6 (27%)	4 (26%)	2 (28%)
Treatments			
Chemotherapy & radiotherapy	3 (14%)	2 (13%)	1 (14%)
Chemotherapy only	6 (27%)	5 (33%)	1 (14%)
No oncology	10 (45%)	8 (53%)	2 (29%)
Palliative care	3 (14%)	0 (0%)	3 (43%)
Cancer staging			
Duke A	3 (14%)	3 (20%)	0 (0%)
Duke B	6 (27%)	3 (20%)	3 (42%)
Duke C	8 (36%)	6 (40%)	2 (29%)
Squamous cell carcinoma	2 (9%)	2 (13%)	0 (0%)
Well differentiated neuroendocrine	1 (5%)	1 (7%)	0 (0%)
Metastases	2 (9%)	0 (0%)	2 (29%)
Behaviours impacting on cancer risk			
Smoker: n (%)	2(9%)	1(7%)	1(14%)
Alcohol consumers: n (%)	15(68%)	10(67%)	5(71%)
Alcohol consumption (units per week): Median (LQ, UQ) Range	10(4, 22) 1 - 70	12.5(3.75, 53.25) 3 - 70	11.0(~)** ~
Alcohol free days: Median (LQ, UQ) Range	4(1, 5) 0 - 6	3.5(1.0, 5.0) 0 - 6	0(~)** ~
Leisure PA (mins): Median (LQ, UQ) Range	480(227, 709) 40 - 2070	480(240, 705) 40 - 2070	480(190, 735) 150 - 1030
Work PA (mins): Median (LQ, UQ) Range	1800(163, 4200) 125 - 4800	200(~)* 125 - 4800	2700(~)* 1800 - 3600
Total PA (work + leisure): Median (LQ, UQ) Range	532(228, 886) 40 - 5250	480(240, 720) 40 - 5250	649(190, 2830) 150 - 4080
Fat rating score[#]: Median (LQ, UQ) Range	32.0(26.75, 41.25) 16 - 64	32.0(27.0, 42.0) 17 - 64	29.0(26.0, 37.0) 16 - 44
Fibre rating score[#]: Median (LQ, UQ) Range	30.5(25.5, 40.0) 10 - 50	31.0(28.0, 40.0) 10 - 50	27.0(24.0, 40.0) 15 - 40

All results are n (%) unless stated otherwise [#]SIMD Scottish Index of Multiple Deprivation

*<4 participants in work **n=1

Programme Implementation

The median time in phase 1 (pre-habilitation) was 15 days. The median time in phase 2 was 36.5 days and phase 3 was 102 days but was frequently extended by clinical problems due to health status post-surgery, treatment responses and pre-existing co-morbidities. Table 2 illustrates the significant and varied challenges experienced by individual participants during the recovery phase. Many patients did not have sufficient time in phase 3 (prior to project end) to enable secondary outcomes to be reliably assessed.

Table 2 Summary of participants' clinical progress during the TreatWELL study

Participant completed study n= 15 Dropped out n=7

1	Biopsy showed advanced disease after patient had undergone baseline measures and the phase 1 LC intervention visit. Patient excluded from further study measures.
2	Surgery as planned but poor postoperative recovery and discharged to a continuing care unit. Intravenous (IV) chemotherapy started after discharge home followed by oral chemotherapy and radiotherapy. Waiting for stoma reversal. All phases of study completed.
3	Surgery as planned. Slow recovery post-surgery and on parenteral nutrition. No adjuvant therapies required. Discharged home with carers twice a day, walking with a Zimmer frame. May have further surgery and did not progress beyond phase 2 in study. Seen at peripheral hospital.
4	Surgery as planned. No adjuvant therapies required. Became worried about recurrence after discharge and had to have psychological support. Hip pain re-started in phase 3. Lung metastases and heart failure diagnosed. Dropped out during phase 3. Patient died.
5	Surgery as planned. No adjuvant therapies required. All study phases completed.
6	Short phase 1. Emergency surgery to de-function bowel (stoma formation). Successful chemotherapy and radiotherapy before main surgery. Phases 2 and 3 switched round for this participant. All study phases completed.
7	Surgery as planned then admission to high dependency unit post-operatively. Discharged but re-admitted for further surgery and stoma formation. Chemotherapy given. All study phases completed.
8	Surgery performed. Further surgery performed for removal of residual tumour. Stoma reversed. No adjuvant therapies required. All study phases completed.
9	Biopsy showed advanced disease after patient had undergone baseline measures. Patient not going ahead for surgery and excluded from further study measures.
10	Surgery as planned and chemotherapy. Admitted with diabetic ketoacidosis but diabetes since resolved. Slow recovery. Phase 1 delivered day before surgery Phase 2 and 3 of study completed.
11	Short phase 1. Surgery performed. No adjuvant therapies required. Completed phase 2 and 3 of the study.
12	Phase 1 delivered day before surgery. Surgery performed. Chemotherapy commenced early due to cancellation in clinic and completed. Phase 2 completed. Wife has health issues which prevented him completing phase 3.
13	Surgery as planned, No adjuvant therapies required. All phases of study completed. Home visits.
14	Surgery as planned and chemotherapy started after surgery. All study phases completed. Seen at peripheral hospital.
15	Surgery as planned and no chemotherapy required. All phases of study completed (short phase 1).Home visits.
16	Surgery as planned, No adjuvant therapies required. All phases of study completed. Home visits.
17	Surgery as planned. Oral chemotherapy after surgery. All phases of study completed.
18	For de-functioning stoma and pre-surgery radiotherapy and chemotherapy. Surgery performed. Lost to follow up as still requiring intensive treatment at study end (phase 1 and 2 only).
19	Surgery as planned but re-admitted. Slow recovery from surgery with significant complications. Phase1, 2 and 3. Dropped out of study during phase 3 as felt back to normal and did not require further support.
20	No phase 1 undertaken. Surgery as planned, long post-operative recovery. No adjuvant therapies required. Phase 2 and 3 of study completed.
21	Surgery performed. No adjuvant therapies required. All phases of study completed. Home visits.
22	Phase 1 delivered day before surgery. Surgery performed. Chemotherapy required. Phases 2 and 3 of study completed.

Total median intervention delivery by lifestyle counsellors was 5 hrs 29 mins. LCs reported that patient engagement was high, with 93-100% being at least "fairly engaged" at all stages. Similarly the LCs reported that participants were receptive and interested in the information being delivered.

LCs rated participants as at least "fairly motivated" to improve diet and physical activity levels. During the immediate recovery stage (phase 2) LCs were most likely to report goal setting for diet and PA as "neither easy nor difficult" (73% and 64% for diet and PA respectively). At the phase 3a time point, LCs rated the ease of goal setting more favourably, with 46% of consultations described as "easy" to set dietary goals and 82% for PA.

Achieved Measurements

Baseline measures were completed on all participants, except in four cases, where the 6 minute walk test had to be excluded due to lack of space in the participant's home. Only 6 out of 33 participants were seen at the end of phase 1 due to the difficulty in fitting in visits prior to surgery. All participants remaining in the study were seen at the end of phase 2, but it was not possible to carry out all anthropometric measurements and walking tests at this point. Walking tests were not possible at the end of phase 3. Questionnaire data were generally well completed however some participants were reluctant to answer sexual function questions (LARS questionnaire) in all phases.

Factors affecting protocol adherence

The LCs reported that they were able to cover most of the intervention components during phase 1 (78% delivery), 3a (73% delivery) and 3b (90% delivery). However, during the post-surgical phase (phase 2), LCs reported difficulties with access to patients. Lifestyle counselling was reported as most challenging during visits 1 (first contact) and 2 (immediately post-surgery). Delivery became more comfortable towards the end, with LCs reporting 70% of the final sessions as "fairly easy" (compared with 39% in Phase 1 and 46% in Phase 2).

The major challenges of intervention delivery reported by the LCs were:

- The short time between diagnosis and surgery
- Participants identifying time to fit in the baseline and intervention visits in addition to diagnostic and treatment preparation schedules
- Seeing patients in phase 2 (short period)
- Difficulties identifying the transition from end of phase 2 and start of phase 3
- Poor clinical progress (some patients were readmitted)
- Due to complications a longer treatment period was required which extended phase 3 beyond the project life
- Mixed messages from NHS staff and TreatWELL LCs

Participants views on acceptability

Of 20 participants who completed phase 2, 14 were invited for interview, 3 declined and 11 participated (7 men and 4 women), with a mean age of 66 ± 6 (range 57 to 75) years. Interviewees were from a range of areas of deprivation.

Most participants recalled that they had been recruited around the time of their diagnosis. For some, this timing appeared to have facilitated participation, as the study offered a potentially beneficial experience on which to focus, taking their mind off their diagnosis and concerns for the future. Several were reassured by the endorsement of colorectal consultants. Generally, the amount of contact, and the balance between visits and telephone calls, appeared acceptable, and the provision of home visits was particularly appreciated. Some appeared a little apprehensive about the prospect of 'going it alone' at the end of the study but they recognised that its end signalled another milestone in their recovery. Participants spoke positively of LCs and felt that LCs had been able to move them gently into doing things they might have been reluctant to do. Some hinted that they had relied on the counsellor for wider emotional support.

The PA advice appeared to have been particularly salient, with most participants being able to describe their PA goals and targets. Pedometers were felt to have been very helpful. Some described having become so fixed on their PA goals that they "over-did things", but most felt that the advice had encouraged them to be more active and to "push" themselves more than they might otherwise have done. Participants generally felt that they had managed to take on board the diet advice, although some had struggled with cutting out 'treats'.

A number of facilitators and barriers to engagement were identified. Prior enjoyment of walking and previous experience of weight loss programmes were both beneficial, as were supportive family members who encouraged adherence to healthy eating and sometimes participated in activity along with the participant. Receiving a diagnosis of cancer was a major motivator for adherence. Participants were determined to overcome their diagnosis and quickly regain their health, not least for significant others. Similarly, participants were motivated to make changes in order to put themselves in the best condition for surgery and to optimise their recovery. One woman was motivated to maintain a healthy weight during her stay in hospital by witnessing fellow patients who were overweight struggling with their mobility. Monitoring progress especially with regard to levels of PA also provided motivation and some enjoyment for participants.

A main factor which negatively affected adherence to the intervention was participants' physical health. Some participants felt too unwell to increase PA, although this was alleviated for some by building strength gradually, whilst others described comorbidities hampering their attempts to be physically active.

Some clinical staff were reported to have advised participants to gain weight by eating whatever they liked and by not discouraging unhealthier foods, in direct contrast to TreatWELL. This inconsistency caused confusion, and participants reported following the advice of clinical staff. Participants also highlighted that NHS staff had little awareness of TreatWELL and appeared to provide little encouragement. More generally, it was noted that nursing staff did not encourage patients to get up and move on the ward.

Secondary Outcomes

There was no change in smoking habits – one of the two smokers at baseline was lost to follow-up and the other smoker continued to smoke. The number of participants who reported consuming alcohol decreased between baseline and end of phase 3 although in some individuals intake increased. PA data shows a positive trend towards increased activity overall. For the 15 who completed the study, minutes of physical activity nearly doubled from a median of 480 (IQ range 240 – 720) per week to 840 (IQ range 330 to 1260). This was largely due to an increase in leisure time activities, but, a decrease in active time at work (few participants continued to work during the study period). Dietary data indicated no increase in

total fat score but a desirable increase in fibre score. Quality of Life data indicated some increase in global health function but also increases in anxiety.

The majority of participants had excess weight (77%) and 40% were obese at baseline (Table 1). None were underweight. At the end of phase 2, body weight had decreased as expected in the post-surgical period. Despite this weight loss, no underweight individuals were detected at the end of phase 3 and the proportion with excess weight remained. The 6 minute walk test indicated no decrease in functional ability by the end of phase 3.

It should be noted however, that all secondary outcome results were obtained principally to test ability to undertake measures and are not powered to detect differences.

DISCUSSION

Whilst it is recognised that pre-surgical (prehab) lifestyle intervention may have significant impact on improving health outcomes in the early months following a diagnosis of colorectal cancer there is little evidence of multi-component intervention RCTs to support investment in this area. This study illustrates the complexities of delivering and evaluating such interventions and highlights issues that need to be addressed prior to progressing further work. The main findings show that it is difficult to recruit at diagnosis because of the multitude of investigations taking place, the staff's perceptions of frailty and age (although all participants were deemed fit for surgery) and the relatively short period available for recruitment, baseline data collection and intervention delivery before surgery. It is notable that a high proportion of participants were male (77%) and whilst national data reports [39] that more men are diagnosed with colorectal cancer compared to women (54% versus 46%), the proportion in this study is higher than anticipated. The reason for this is not clear but does indicate the need to explore this in future work. Phase 2 was predictably short for most patients, but longer in those who had previous illness or had developed post-surgical complications. It should be noted that because patients were recruited at diagnosis, the extent of the disease (i.e. stage) was unknown and complications were unpredictable. Many participants spent insufficient time in phase 3 (prior to study end) for the impact of the intervention to be assessed, highlighting the need for a longer study duration for final outcome measurements. The clinical pathways of participants were unpredicted and impacted on study retention. The hardest challenge in delivery was when to introduce the next phase of the intervention (phase 2 to phase 3) because many participants had complex journeys through treatment. These findings highlight that compliance with a strict RCT protocol for this type of intervention is likely to be difficult. Outcome measures were largely acceptable, although consideration should be given to whether the more sensitive questions on quality of life are required. Participant views suggest the intervention was largely acceptable, and that the focus on physical activity was appropriate. The high number of patients with excess body weight at study recruitment (and exit) is of concern and a future trial encompassing weight loss is likely to need long term support and follow up.

Whilst our recent intervention study [40] has tested the feasibility of undertaking lifestyle interventions in people at high risk of colorectal (and breast) cancer, this study (to the best of our knowledge) is the first to have offered a comprehensive lifestyle intervention at diagnosis with support before, during and after treatment in patients with colorectal cancer. Although the study is small and was undertaken in a single NHS health board, the results have highlighted a wide range of issues that would need to be addressed in a full trial of a multi-component intervention. The lack of randomisation means that it is not possible to assess whether uptake to a randomised trial with control condition would be similar.

Moug et al [41] have recently reviewed 14 randomised controlled trials in this patient group and concluded that lifestyle interventions are feasible in patients with CRC. However, it is notable that there were no RCTs of tobacco and alcohol. In general, they reported variable recruitment rates but good adherence and retention (as is the case in our own study). Ravasco et al [13] have demonstrated positive outcomes in CRC patients referred for radiotherapy (irrespective of other therapies provided) after dietary counselling. However, other trials of diet and lifestyle have been focussed on patients after the end of treatment [14, 42, 43]. The challenges to conducting a trial in this patient group are similar to those described by Hubbard et al [44] in feasibility work of a pragmatic RCT for a group based rehabilitation programme for CRC survivors which reported a high likelihood of recruitment bias, potential of sub-optimal completion of outcome data, missing data and poor intervention adherence.

It is important to note that no specific progression criteria were identified (or agreed) for trial progression in the current study, but each of the parameters identified are relevant in decisions around future progression (recruitment, retention, programme implementation, achieved measures, fidelity, factors affecting protocol adherence and acceptability). The findings show that the recruitment was too low (both due to eligibility, people approached and willingness to participate), too many participants failed to complete because of major health problems, the intervention delivery varied widely from the protocol (in terms of timing and approaches) and the number of achieved measures (notably at end of phase 1) would be inadequate to provide any indication of impact.

In accordance with Thabane et al [45] there are four possible progression outcomes as follows *(i)* Stop - *main study not feasible; (ii)* Continue, but modify protocol - *feasible with modifications; (iii)* Continue without modifications, but monitor closely - *feasible with close monitoring and (iv)* Continue without modifications - *feasible as is*.
Our results suggest that it would be plausible to continue but that the protocol should be modified and further feasibility testing undertaken prior to a full trial

The current intervention approach is ambitious, but could be refined for testing in an RCT if all visits can be linked more closely with clinical appointments, measurement visits are reduced and if the clinical team were encouraged to help support lifestyle changes. Fundamentally interventions being tested should be scalable, durable and cost effective [46]. Whilst there is much practical guidance on diet and lifestyle for cancer survivors [47, 48] and interventions which have been demonstrated to be safe and feasible there remains a need for studies that can demonstrate the impact of lifestyle intervention on disease outcomes. Research in this area requires multilevel approaches with full support from health service staff (both in recruitment and support for lifestyle action), intervention staff for the delivery of tailored, personalised approaches and patient interest and advocacy.

CONCLUSIONS

To make this intervention feasible for testing as a full RCT, further research is required on a) recruitment optimization b) appropriate assessment tools c) protocols for phase 2 and 3 which can build in flexibility and d) ways for NHS staff to facilitate the programme.

Figure legend

Figure 1 TreatWELL recruitment CONSORT flowchart

Figure 2 TreatWELL study progression CONSORT flowchart

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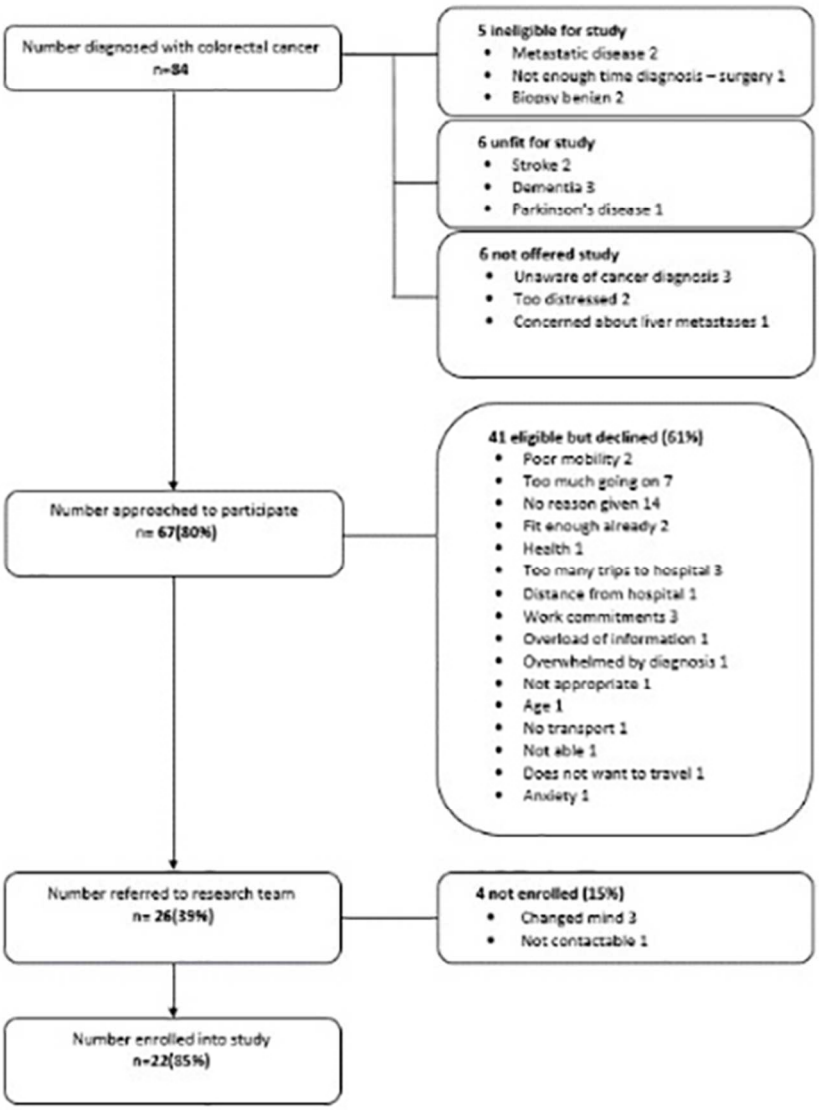

Figure 1 TreatWELL recruitment CONSORT flowchart

46x64mm (300 x 300 DPI)

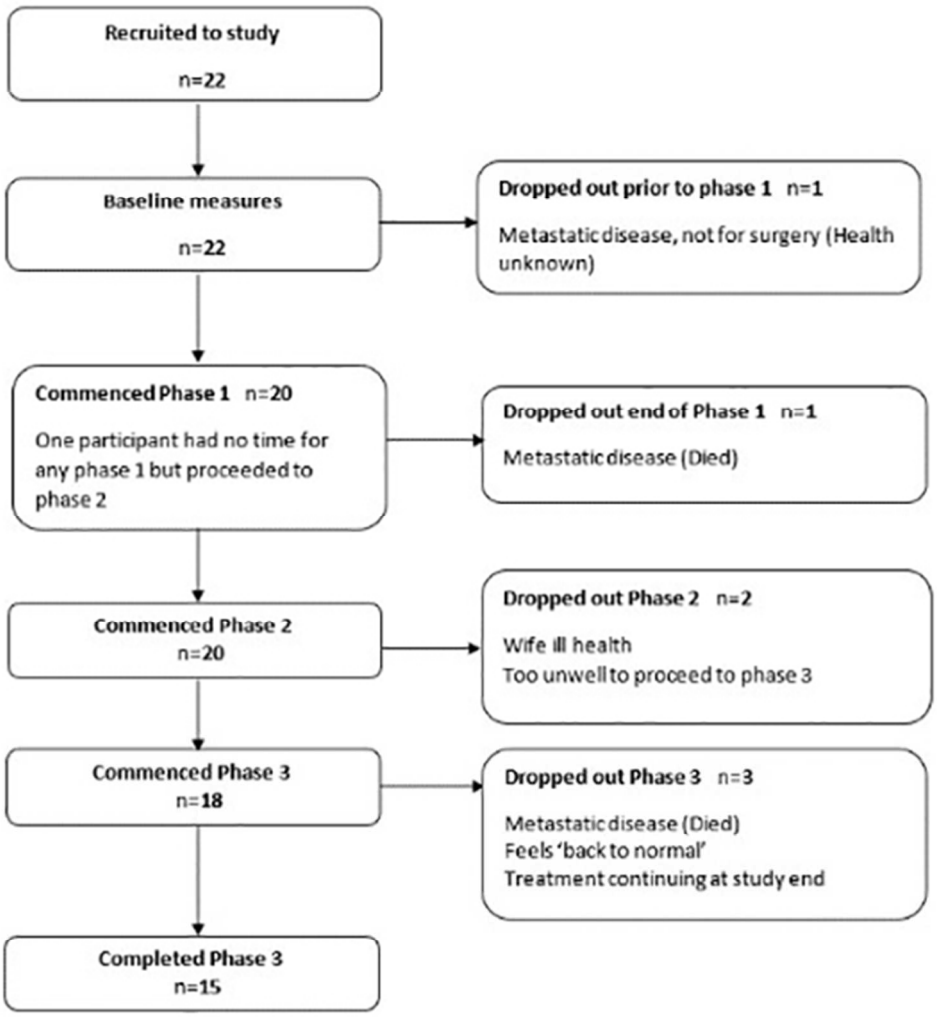

Figure 2 TreatWELL study progression CONSORT flowchart

55x59mm (300 x 300 DPI)

Appendix 1 TreatWELL intervention delivery plan and resources

Phase 1 Prehabilitation

a) Delivery mode:

Face to face study consultation visit 1 (1 hour) (hospital/research centre). All participants were encouraged to bring a support friend/family member

Consultation Focus:

Getting fit for surgery

- Education and endorsement on smoking, alcohol, physical activity, fruit and vegetables (FAV))

Resources:

- Fast track smoking cessation card
- Leaflet *How to stop smoking and stay stopped* booklet
- AUDIT alcohol assessment
- NHS Scotland alcohol booklet: *Making a Change*
- Macmillan DVD and booklet on physical activity
- DoH physical activity guidelines
- Pedometer

Behaviour change techniques

- Motivational Interviewing questions
- Goal setting for 2 health behaviours (smoking, alcohol, physical activity, diet, FAV)
- Implementation Intentions (smoking, alcohol, physical activity, FAV)
- Self-monitoring (activity diary)

AND Telephone home calls (1 to 2) 10-15 minutes (home)

Phase 2 Surgical Recovery

a) Delivery mode:

Brief face to face support meeting (10- 15 min; in hospital ward)

Consultation Focus:

Recovery and continuing support

- Consistent with Enhanced Recovery After Surgery protocol (ERAS)
- Support about relevant post-operative physical activity
- Education and endorsement about diet (regular meals, sugary drinks, FAV)
- Advice offered on smoking and alcohol as appropriate

Resources:

- Bowel Cancer UK booklets: *Eating and Drinking During Treatment, Fibre after Bowel Cancer* (as appropriate),
- Phase 2 activity diary

Behaviour change techniques

Phase 2 (early phase 3)

b) Delivery mode:

Brief telephone/ward contacts 10-15 minutes

Consultation Focus:

Recovery and continuing support

- 1st visit/call Supportive for managing goals
- 2nd visit/call Responding to queries about diet, physical activity, alcohol, smoking

Phase-3 Post surgical/adjuvant therapy/ recovery

a) Delivery mode:

Face to face consultation study visit 2 (1 hour; hospital/ research centre)

Participants not on chemotherapy Visit takes place start of phase 3	**Participants on Chemotherapy** Visit takes place half way through chemotherapy
Consultation Focus: A new start • Diet, Keep active (walk and talk), • Management of weight **Resources**: • Eatwell plate • 7 day food and drink diary • Booklet: *Thinking about becoming more active?* • 12 week activity diary • Resistance bands • NHS Tayside information *Helping you manage your weight* • Information about personalised weight management • Bowel Cancer UK booklet: *Losing Weight Safely* • Weight awareness plan **Behaviour Change techniques** • Goal setting for two health behaviours physical activity, smoking, alcohol, diet • Implementation intentions • Self-monitoring (body weight log)	**Consultation Focus** A new start • Diet, Keep active (walk and talk), • Introduce weight management concepts **Resources**: • Eatwell plate • 7 day food and drink diary • Booklet: *Thinking about becoming more active?* • 12 week activity diary • Resistance bands **Behaviour Change techniques** • Goal setting for two health behaviours physical activity, smoking, alcohol, diet • Implementation intentions • Self-monitoring (body weight log)

Face to face consultation study visit 3 (1 hour; hospital/research centre)

Participants with no chemotherapy Scheduled 4 weeks post consultation study visit 2	**Chemotherapy** Visit takes place at end of chemotherapy
Consultation Focus: • "Future planning" • Education and endorsement on healthy eating, • Reinforce physical activity advice **Resources**: • *TREATWELL Getting active and eating well after Bowel Cancer treatment* • Calories and alcohol information **Behaviour Change techniques**	**Consultation Focus**: • "Future planning" • Management of weight • Education and endorsement on healthy eating • Reinforce physical activity advice **Resources**: • NHS Tayside information *Helping you manage your weight* • Information about personalised weight management • Bowel Cancer UK booklet: *Losing Weight Safely* • Weight awareness plan • *TREATWELL Getting active and eating well after Bowel Cancer treatment* • Calories and alcohol information **Behaviour Change techniques**

And up to 8 Brief telephone calls 10-15 minutes at home

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5, 6
	2b	Specific objectives or research questions for pilot trial	6
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6-9
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8, 9
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	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	6
	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	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
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	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	8, 9
Results			
Participant flow (a diagram is strongly recommended)	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	10, Figs 1 & 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	10, 11, Figs 1 & 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	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	11
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	12
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	12-16
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
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	2,16, 17
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	16, 17
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	16, 17
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	16, 17
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3
	26	Ethical approval or approval by research review committee, confirmed with reference number	3

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.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.