Detailed protocol for the lifestyle intervention in the BeWEL randomised controlled trial of weight loss in adults who have had a colorectal adenoma.

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Complete List of Authors:	caswell, stephen; University of Dundee, Centre for Research into Cancer Prevention and Screening Craigie, Angela; University of Dundee, Centre for Research into Cancer Prevention and Screening, Medical Research Institute, University of Dundee Wardle, Jane; University College London, Dept. of Epidemiol Stead, Martine; University of Stirling and the Open University, Institute for Social Marketing Anderson, Annie; University of Dundee, Centre for Research into Cancer Prevention and Screening, Medical Research Institute
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Abstract

Introduction: The BeWEL study is aimed at assessing the impact of a personalised lifestyle programme on body weight in people at risk of developing colorectal adenomas. The study is a two-arm, multicentre randomised controlled trial comparing the BeWEL lifestyle programme against usual care. Over 12 months, 316 people who have had a colorectal adenoma removed through the national screening programme will be randomised to provide 80% power to detect a weight loss (primary outcome) of 7% over 12 months.

Methods: The 12 month intervention will be delivered by lifestyle counsellors via three face-to-face visits followed by nine monthly telephone support calls. The primary outcome will be communicated at the first contact. Consultant endorsement for the study will be stressed. An individualised caloric prescription based on estimates for weight maintenance minus 600kcals will be calculated. Motivational interviewing techniques will be used to identify personal motivations for weight change and ways to improve perceived self-efficacy. The programme will utilise personalised diet and physical activity data from baseline measures to set behavioural goals. A range of behavioural strategies will be employed to support lifestyle change including goal setting, identifying specific implementation intentions, self-monitoring, feedback and re-enforcement. To facilitate behaviour change, participants will be offered access to an equipment tool kit (e.g. steppers, hand blenders). Emphasis will be placed on self-monitoring body weight, and weighing scales will be provided. Programme acceptability will be explored post-intervention with in-depth interviews. Compliance and impact will be assessed by baseline and follow-up measures of diet by self-report, activity by accelerometry and anthropometry.

Ethics and Dissemination: Ethical Approval has been obtained from the Tayside Committee on Medical Research Ethics. The detailed intervention protocol provides a standardised approach to intervention content and delivery procedures for use in diet, physical activity and weight loss trials.

Summary

Article Focus

- Design of diet and physical activity intervention for weight loss
- Detailed protocol of content and delivery of intervention

Key messages

- Process of combining educational, motivational and behavioural strategies
- Developing the teachable moment in the colorectal cancer screening setting

Strengths and limitation

- Minimal contact intervention over 12 months
- Potential change in control group through study involvement

Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed cancer in the UK [1]. Most cases occur in people over 50 years and CRC often co-exists with other diet-related disorders including obesity, type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD) [2-4]. These diseases share risk factors related to the metabolic syndrome including high body mass index (BMI), abnormal lipids and markers of insulin resistance indicating common aetiological pathways [5].

The WCRF (2007) review of Food, Nutrition, Physical Activity and the Prevention of Cancer provides comprehensive evidence on diet and obesity related risk factors and colorectal cancer (CRC) [6]. The main (convincing level) factors identified by WCRF to increase risk were high body fat, red and processed meat and alcohol intake, whereas high levels of physical activity and foods containing fibre were factors that (probably) decreased risk.

Weight gain in adulthood is associated with the development and recurrence of colorectal adenomas (pre-malignant lesions), while weight loss is associated with reduced recurrence rates [7-9]. Therefore, it would seem prudent to recommend weight loss (through increased physical activity and dietary adjustment) to overweight adults who have experienced an adenoma in order to minimise the risk of CRC and other related co-morbidities. Whilst surveillance colonoscopy is offered to patients who have had adenomas, colonoscopy procedures may still miss adenomas and several studies have reported interval cancers diagnosed between examinations [10-12]. Current evidence suggests that the risk of new adenomas is around 40% after 3 years; although this may be higher in the morbidly obese [13]. Furthermore, the underlying modifiable risk factors which influence the development of new adenomas remain after colonoscopy.

The BeWEL study design and evaluation protocol are described elsewhere [14]. In brief, this is a two-arm, multicentre, randomised controlled trial comparing the BeWEL lifestyle programme (targeting behaviour change with regards to diet, physical activity and weight loss) against usual care. The intervention will be delivered over 12 months and aims to achieve complete data from 266 adults aged 50 to 74 years who have undergone colonoscopy for adenoma removal. The primary outcome is change in body weight.

The behavioural context for the intervention builds on the observation that programmes which target high risk groups are more effective than those targeting the population at large [15]. In addition, individuals who have had a health scare (e.g. diagnosis of an adenoma) may be in a "teachable moment" in which they are more motivated to engage with and adhere to lifestyle advice [16]. This may depend on them experiencing an increase in perceived risk of disease (with expectations of negative consequences) and having an emotional response that triggers a redefinition of their self-image or role [17].

The lifestyle goals of the BeWEL intervention were based on the diabetes prevention trials which have shown that lifestyle interventions that achieve a weight loss of 7% of initial body weight and at least 150 minutes/week of moderate intensity activity in adults with a BMI >25kg/m^2 reduce the incidence of T2DM [18-21]. The behavioural characteristics of the intervention delivery were largely based on the US diabetes prevention programme [22], with the addition of emphasis on the importance of regular self-weighing which is widely associated with greater weight loss and weight prevention [23-24].

The final design of the intervention protocol was informed by formative social marketing research with the client group [25], evidence on behaviour change (as described above) and practical (resource) considerations. The aim of the current paper is to detail the procedures and content of the lifestyle programme used with the intervention group as described in the final study protocol [14].

Methods

The BeWEL study will recruit 316 participants who have had a colorectal adenoma removed following their participation in the Scottish Bowel Screening programme. Of these, 158 (50%) will be randomised to the intervention arm of the BeWEL trial (14). The intervention is designed to involve multiple contacts with Lifestyle Counsellors (LC's) over a 12 month period and all participants will be invited to identify a partner or friend to provide support. Three face-to-face visits in the first three months will be followed with nine telephone support calls spaced equally until completion of the study with follow up assessments being taken at 12 months. Full details of evaluation methods of the study, for which the primary outcome is body weight, are provided elsewhere [14].

Lifestyle counsellors (LCs) will be trained to deliver the intervention protocol which focuses on four strategies for assisting behaviour change. Firstly, the LCs will aim to increase knowledge about why the changes are advisable, secondly, the magnitude and nature of change required will be discussed, thirdly, techniques aimed at motivating change will be used, and finally strategies to improve self–efficacy about changing diet and activity will be provided.

After providing written, informed consent participants will undertake their first intervention visit. The lifestyle counsellors will begin their introduction by discussing the process through which colorectal cancer typically develops, i.e. the adenoma-carcinoma sequence [26]. The counsellors will highlight the importance of diet, activity and body weight in the prevention of colorectal cancer and also emphasise how weight loss might reduce the risk of other diseases or co-morbidities. It will then be made clear to participants that the principle aim of the study is to promote weight loss through diet and activity. Before addressing specific components of the intervention participants will be reminded that the changes being promoted are endorsed by the senior hospital consultants as indicated in the study invitation letter.

The target goal of a 7% reduction in body weight will be communicated at the first contact. An individualised energy prescription for weight loss will be identified by in three steps. Initially their requirements for weight maintenance will be calculated using Schofield equations [27] incorporating body weight, gender and age. This will then be multiplied by their current physical activity level before a caloric restriction of minus 600 kcals is applied.. The composition of the diet will be in line with current healthy eating advice (with caution over consumption of excess red and processed meat, and limiting intake of energy-dense food and drinks) and increased physical activity. No pharmacological agents will be provided or promoted.

The general educational components of healthy eating and active living will initially be explained using the British Heart Foundation (2010) booklet “So you want to lose weight for good” (which includes the Food Standards Agency “Eatwell” plate model (the national food guide) [28]. Portion guidance and information on energy dense food and drinks (highlighting fast foods and sugary drinks) will be provided with reference to the information in the BHF guide. With respect to physical activity, demonstrations will be given on “brisk walking” and a pedometer provided for self-monitoring. The translation of 7% weight loss will be provided as a personal weight loss target for the 12 month period. This will include guidance on a personalised -600 kcal energy deficit diet (based on estimated Basal Metabolic Rate), provided on the basis of food group portion sizes and portion frequencies. Options on following this completely (e.g. starting on -600 kcals) from day 1 or building up to -600kcals will be discussed with reference to the weight loss requirements over a 12 month period.

Motivational interviewing [29] will be utilised to explore self-assessed confidence, ambivalence and personal values concerning weight change. A 24-hour recall of dietary intake will be taken to promote discussion around current diet and allow counsellors to introduce the concept of personalised dietary change. Study participants will have worn a SenseWear Pro_3 physical activity monitor (Body Media Inc.) for seven days to provide baseline physical activity records (also worn by the usual care group), prior to being visited by the lifestyle counsellor. The output from the monitors will be utilised to provide feedback on current activities and to promote discussion around opportunities to increase leisure time activity where possible.

To assist change in both diet and physical activity, participants will be encouraged to focus on one topic (diet or physical activity) for the remainder of visit one, and the remaining topic on visit two, generally advising that the strongest area of existing success is likely to be the best to begin with. To aid improvements in self- efficacy, participants will be encouraged to identify specific behavioural goals [30] and make short term specific implementation intentions [31]. Success or failure with these goals will be discussed at follow up visits. Self-monitoring will also be encouraged and participants will be presented with body weight scales for weekly weighing, pedometers to monitor daily step counts, and log books. A number of behavioural and re-enforcement techniques will be employed in this part of the counselling session including tool kits to assist change, practical discussions on food preparation (or equipment demonstrations) and self-recording sheets for the specific implementation intentions identified. Tool-kits will include items for loan including kitchen gadgets such as salad spinners and hand blenders, and physical activity tools such as steppers, hand weights, hula hoops, exercise DVDs and walking poles. In addition, to encourage loyalty to the study all participants will be given tools with the BeWEL logo: a water bottle to re-enforce the message to reduce sugary drink intake, and a fabric bag for transporting scales home and/or to act as reminder for healthy eating while shopping.

The first session will finish with a return to weight matters, and instructions for self-monitoring and recording of weight will be given. Contact details for professional support will be provided and the next appointment made. Visits 2 and 3 will have similar formats, checking wellbeing discussing and providing feedback on progress and experiences, exploring areas of difficulty and providing encouragement. Visit 2 will also encourage a focus on the second topic area (diet or activity) not selected in visit 1. The content of all visits is presented in table 1.

By the end of visit 3, all participants will have identified a specific set of personalised diet and activity implementation intentions and weight loss goals for the remainder of the study.

The remainder of the intervention will be delivered by telephone (Table 2). Nine further telephone calls from three to twelve months will be completed before participants return to the research centre for follow up measures. LCs will continue to support BeWEL participants in their attempts to lose the target 7% body weight. Participants who do achieve this target but who remain overweight will be encouraged to continue the weight loss programme. Participants who have met their target weight loss (and are no longer overweight) will be encouraged to adopt a weight maintenance approach.

Follow up calls will begin with a general introduction about mental and physical wellbeing and LC's will attempt to elicit participant's views on making lifestyle change. LC's will be responsible for checking participant's progress since visit 3 and the first follow-up at three months, discussing areas of success and difficulty. LC's will provide the participant with further verbal (and where appropriate written) and personalised lifestyle advice to promote optimal dietary intake, physical activity and weight loss. Personalised goals will be agreed and updated through discussion with the participant and the LC's will keep records of these to provide personalised feedback and continuity through to follow-up at twelve months.

Lifestyle counsellors will keep participant notes recording the application of the above procedures and these will be reported to the study team as an indirect check on intervention fidelity.

Programme acceptability will be explored post-intervention with in-depth exit interviews (undertaken by staff not involved with programme delivery) with a random sample of 30 intervention participants. Interviews will cover participants' initial expectations and motivations regarding the programme, the extent to which these were met or not by their subsequent experiences, and factors influencing their ability to make the recommended lifestyle changes [14]. A thematic analysis of interview transcripts will be undertaken, exploring such themes as what factors influence decisions to engage in the programme, how uptake is influenced by socio-economic status, the practical barriers and opportunities for facilitating physical activities and changes in dietary habits, and the perceived acceptability of the programme to participants and families.

The impact of specific component parts on outcomes will not be assessed, but reported compliance with diet and physical activity goals will be available from post intervention measures [14]

Ethics and Dissemination

Ethical approval for the intervention content was obtained from the Tayside Committee on Medical Research Ethics.

The detailed intervention protocol provides a standardised approach to intervention design, delivery and content for use in diet, physical activity and weight loss trials. The rationale for the total amount of contact time (5.25 hours over a 12 month period) with counsellors would be similar to monthly weight management appointments in NHS (primary care) but less than commercial slimming clubs. Minimal contact enables costs to be minimised but professional support to be retained.

Group work was not considered because of the geographical spread of the regions in which the trial is being carried out, and the subject face to face time burden. Minimal contact approaches such as phone and email have been shown to produce promising results for weight loss with high frequency calls from a health professional producing similar results to high frequency face to face lifestyle modification counselling [32-33]

The content of the intervention was based on current guidelines for weight management from the Scottish Intercollegiate Guidelines Network [34] which recommends a combination of physical activity, diet and behavioural therapy components. The behavioural strategies used draw on evidence for successful dietary changes from Ammerman et al [35] and weight loss management from the National Institute for Health and Clinical Excellence [36].

The fidelity of the intervention content and delivery will inevitably vary by the individual style of each lifestyle counsellor but training sessions have emphasised the need to deliver all components but modify to suit the participants' individual circumstances e.g. disability, economic circumstances or learning difficulties. Whilst family/friend support is recommended it is recognised that this will not be possible to access in all cases.

The ease of undertaking all contacts with participants, delivering the intervention components and feedback from participants will provide insight to the practical acceptability of this theory based, practice focussed intervention design.

Trial registration

The trial is registered with Current Controlled Trials (International Standard Randomised Controlled Trials No: ISRCTN53033856).

List of abbreviations

CRC: Colorectal cancer

T2DM: Type 2 diabetes mellitus

CVD: Cardiovascular disease

WCRF: World Cancer Research Fund

LCs: Lifestyle Counsellors

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Table 1- Delivery and Content of Counsellor visits (contacts 1-3)

	Visit 1	Visit 2	Visit 3
Contact	Face to face	Face to face	Face to face
Time line	Following baseline assessment	Week 6-8	Three months
Duration	90 mins	45 mins	45 mins
Who Delivers	Trained Counsellor	Trained Counsellor	Trained Counsellor
Intervention location	Home/Research Centre	Home/Research Centre	Home/Research Centre
Social support	Invited friend / partner/family member	Invited friend / partner / family member	Invited friend / partner / family member
Introduction	Check nurse assessment • Importance of lifestyle change • Consultant endorsement • Identify 12 month weight loss target	• Current well-being • Experience of making change • Importance of modest change • Building towards 12 month weight loss target	• Current well being • Experience of making change • Importance of modest change • Building towards 12 month weight loss target
Motivational approaches	24 hour dietary recall / activity assessment • Identify perceived diet/activity challenges • Identify self-assessed motivations, confidence, ambivalence and personal value regarding weight change	Identify Self monitored weight • Provide feedback • Provide encouragement • Identify self- assessed motivations, confidence, ambivalence and personal values re change	Identify Self monitored weight • Provide feedback • Provide encouragement • Identify confidence and support needs
Education - General	Healthy Eating and Activity Principles • Portion size • Energy dense food and drinks • Breakfast meals and snacks • Activity and Inactivity	Discuss experience of changing diet and activity referring back to perceived challenges at visit 1. Check for queries , or areas of confusion or elaboration	Discuss experience of changing diet and activity referring back to perceived challenges at visit 1 and 2 Check for queries , or areas of confusion or elaboration

	Visit 1	Visit 2	Visit 3
	Demonstration of brisk walking +pedometer	Discuss walking + pedometer	Discuss walking + pedometer
Education – Personalised	Structured weight loss programme -600kcal diet prescription plan	Discuss progress towards achieving -600 kcals diet	Discuss progress towards achieving -600 kcals diet
Behavioural and re-enforcement techniques **DIET or ACTIVITY**	Introduce Diet or Activity focus 1	Discuss self-monitoring of focus 1 Provide positive feedback Identify challenges Discuss maintenance Introduce Diet or Activity focus 2	Discuss self-monitoring of focus 2 Provide positive feedback Identify challenges Discuss maintenance of focus 1 and 2 Negotiate key long term diet and activity goals based on: Perceived achievements Summarise success
Behavioural and re-enforcement techniques **WT MANAGEMENT**	Provide body weight scales Explanation of self-monitoring procedures Remind about 12month goal	Re-enforce body weight techniques	Check body weight scales and the need for continued monitoring
Professional support	Provide tel and email contact details Identify next 2 appointments	Confirm next appointment and identify date for call 1	Confirm call 1 and identify date for call 2

Table 2 Telephone intervention for contacts 4-12

	Contacts 4-12
Contact	Telephone
Time line	Following on from 3rd face to face contact until 12 month follow up assessment.
Duration	10-15 mins
Who Delivers	Trained Counsellor
Introduction	General exchange about mental and physical health Elicit participant's overview on progress and change made Re-enforce importance of modest behaviour change for health benefit Importance of change and building towards 12 month weight loss target. 3 months gone but 9 months to continue improvement.
Motivational approaches	Check self-monitoring records Identify perceived diet/activity challenges Identify self-assessed motivations, confidence, ambivalence and personal value re weight change
Informing Change	Re-enforce portion size guidance/energy dense foods/energy dense drinks Importance of remaining active
Personal Goals (implementation intentions)	Continue to focus on short term implementation intentions and review these at next call.
Setting long term goals	Identify perceived achievements and summarise success Re-evaluate confidence, motivation and importance of changes made
Professional support	Make appointment for next telephone call but re-iterate you can respond to questions before this call as they arise.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 3
	2b	Specific objectives or hypotheses	Page 4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	Page 4
	4b	Settings and locations where the data were collected	Page 4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 14 and 15
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Described elsewhere see page 3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	Described elsewhere see page 3
	7b	When applicable, explanation of any interim analyses and stopping guidelines	DMC reported elsewhere see page 3
Randomisation:			Described elsewhere see page 3
Sequence	8a	Method used to generate the random allocation sequence	

generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Described elsewhere see page 3
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	Described elsewhere see page 3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	statistician
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Described elsewhere see page 3
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Described elsewhere see page 3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Described elsewhere see page 3
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Will be reported elsewhere
	13b	For each group, losses and exclusions after randomisation, together with reasons	Will be reported elsewhere /a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Will be reported elsewhere
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Will be reported elsewhere
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	Will be

		by original assigned groups	reported elsewhere
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Will be reported elsewhere
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Will be reported elsewhere
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	SAE's are being recorded
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Will be reported elsewhere
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Will be reported elsewhere
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Will be reported elsewhere
Other information			
Registration	23	Registration number and name of trial registry	Page 2
Protocol	24	Where the full trial protocol can be accessed, if available	Page 3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 9

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 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.

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Complete List of Authors:	caswell, stephen; University of Dundee, Centre for Research into Cancer Prevention and Screening Craigie, Angela; University of Dundee, Centre for Research into Cancer Prevention and Screening, Medical Research Institute, University of Dundee Wardle, Jane; University College London, Dept. of Epidemiol Stead, Martine; University of Stirling and the Open University, Institute for Social Marketing Anderson, Annie; University of Dundee, Centre for Research into Cancer Prevention and Screening, Medical Research Institute
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Abstract

Introduction: The BeWEL study is aimed at assessing the impact of a personalised lifestyle programme on body weight in people at risk of developing colorectal adenomas. The study is a two-arm, multicentre randomised controlled trial comparing the BeWEL lifestyle programme against usual care. Over 12 months, 316 people who have had a colorectal adenoma removed through the national screening programme will be randomised to provide 80% power to detect a weight loss (primary outcome) of 7% over 12 months.

Methods: The 12 month intervention will be delivered by lifestyle counsellors via three face-to-face visits followed by nine monthly telephone support calls. Consultant endorsement for the study will be stressed. An individualised caloric prescription based on estimates for weight maintenance minus 600kcals will be calculated. Motivational interviewing techniques will be used to identify personal motivations for weight change and ways to improve perceived self-efficacy. The programme will utilise personalised diet and physical activity data from baseline measures to set behavioural goals. A range of behavioural strategies will be employed to support lifestyle change including goal setting, identifying specific implementation intentions, self-monitoring and feedback. Emphasis will be placed on self-monitoring body weight, and weighing scales will be provided. Programme acceptability will be explored post-intervention with in-depth interviews. Compliance and impact will be assessed by baseline and follow up measures of diet by self-report, activity by accelerometry and anthropometry.

Ethics and Dissemination: Ethical Approval has been obtained from the Tayside Committee on Medical Research Ethics. Dissemination of results will focus on publications in peer reviewed journals, presentations at national/international cancer meetings and NHS groups. In addition the work will be communicated to the public through forums such at The Scottish Cancer Prevention Network (http://www.cancerpreventionscotland.co.uk/).

The trial is registered with Current Controlled Trials (International Standard Randomised Controlled Trials No: ISRCTN53033856).

Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed cancer in the UK [1]. Most cases occur in people over 50 years and CRC often co-exists with other diet-related disorders including obesity, type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD) [2-4]. These diseases share risk factors related to the metabolic syndrome including

high body mass index (BMI), abnormal lipids and markers of insulin resistance indicating common aetiological pathways [5].

The WCRF (2007) review of Food, Nutrition, Physical Activity and the Prevention of Cancer provides comprehensive evidence on diet and obesity related risk factors and colorectal cancer (CRC) [6]. The main (convincing level) factors identified by WCRF to increase risk were high body fat, red and processed meat and alcohol intake, whereas high levels of physical activity and foods containing fibre were factors that (probably) decreased risk.

Weight gain in adulthood is associated with the development and recurrence of colorectal adenomas (pre-malignant lesions), while weight loss is associated with reduced recurrence rates [7-9]. Therefore, it would seem prudent to recommend weight loss (through increased physical activity and dietary adjustment) to overweight adults who have experienced an adenoma in order to minimise the risk of CRC and other related co-morbidities. Whilst surveillance colonoscopy is offered to patients who have had adenomas, colonoscopy procedures may still miss adenomas and several studies have reported interval cancers diagnosed between examinations [10-12]. Current evidence suggests that the risk of new adenomas is around 40% after 3 years; although this may be higher in the morbidly obese [13]. Furthermore, the underlying modifiable risk factors which influence the development of new adenomas remain after colonoscopy.

The BeWEL study design and evaluation protocol are described elsewhere [14]. In brief, this is a two-arm, multicentre, randomised controlled trial comparing the BeWEL lifestyle programme (targeting behaviour change with regards to diet, physical activity and weight loss) against usual care. The intervention will be delivered over 12 months and aims to achieve complete data from 266 adults aged 50 to 74 years who have undergone colonoscopy for adenoma removal. The primary outcome is change in body weight.

The behavioural context for the intervention builds on the observation that programmes which target high risk groups are more effective than those targeting the population at large [15]. In addition, individuals who have had a health scare (e.g. diagnosis of an adenoma) may be in a “teachable moment” in which they are more motivated to engage with and adhere to lifestyle advice [16]. This may depend on them experiencing an increase in perceived risk of disease (with expectations of negative consequences) and having an emotional response that triggers a redefinition of their self-image or role [17].

The lifestyle goals of the BeWEL intervention were based on the diabetes prevention trials which have shown that lifestyle interventions that achieve a weight loss of 7% of initial body weight and at least 150 minutes/week of moderate intensity activity in adults with a BMI >25kg/m^2 reduce the incidence of T2DM [18-21]. The behavioural characteristics of the intervention delivery were largely based on the US diabetes prevention programme [22], with

the addition of emphasis on the importance of regular self-weighing which is widely associated with greater weight loss and weight prevention [23-24].

The final design of the intervention protocol was informed by formative social marketing research with the client group [25], evidence on behaviour change (as described above) and practical (resource) considerations. The aim of the current paper is to detail the procedures and content of the lifestyle programme used with the intervention group as described in the final study protocol [14].

Methods

The BeWEL study will recruit 316 participants who have had a colorectal adenoma removed following their participation in the Scottish Bowel Screening programme. Of these, 158 (50%) will be randomised to the intervention arm of the BeWEL trial (14). The intervention is designed to involve multiple contacts with Lifestyle Counsellors (LC's) over a 12 month period and all participants will be invited to identify a partner or friend to provide support. Three face-to-face visits in the first three months will be followed with nine telephone support calls spaced equally until completion of the study with follow up assessments being taken at 12 months.

Any serious adverse events (SAEs) experienced by participants will be reported to the study sponsor, NHS Tayside Research and Development (administration), Trial Management Committee, Trial Steering Committee, Data Monitoring and Ethics Committee and the participants' General Practitioner. In the event that an SAE is considered to be related to the trial intervention, clinical judgement and the participant's preference will inform any decision whether the participant will be withdrawn from the trial, or may withdraw electively. Under no circumstances, initiated by the occurrence of an SAE or otherwise, is a participant permitted to change group allocation. All SAEs and any consequent decisions for participant retention, are reported appropriately. A review of all adverse events and SAEs will also be undertaken at regular intervals by the Data Monitoring and Ethics Committee to ensure any differential rate between groups is identified. Full details of evaluation methods of the study, for which the primary outcome is body weight, are provided elsewhere [14].

Lifestyle counsellors (LCs) will be trained to deliver the intervention protocol which focuses on four strategies for assisting behaviour change. Firstly, the LCs will aim to increase knowledge about why the changes are advisable, secondly, the magnitude and nature of change required will be discussed, thirdly, techniques aimed at motivating change will be used, and finally strategies to improve self–efficacy about changing diet and activity will be provided.

After providing written, informed consent participants will undertake their first intervention visit. The lifestyle counsellors will begin their introduction by discussing the process through which colorectal cancer typically develops, i.e. the adenoma-carcinoma sequence [26]. The counsellors will highlight the importance of diet, activity and body weight in the prevention of colorectal cancer and also emphasise how weight loss might reduce the risk of other diseases or co-morbidities. It will then be made clear to participants that the principal aim of the study is to promote weight loss through diet and activity. Before addressing specific components of the intervention participants will be reminded that the changes being promoted are endorsed by the senior hospital consultants as indicated in the study invitation letter.

The target goal of a 7% reduction in body weight will be communicated at the first contact. An individualised energy prescription for weight loss will be identified in three steps. Initially their requirements for weight maintenance will be calculated using Schofield equations [27] incorporating body weight, gender and age. This will then be multiplied by their current physical activity level before a caloric restriction of minus 600 kcals is applied.. The composition of the diet will be in line with current healthy eating advice (with caution over consumption of excess red and processed meat, and limiting intake of energy-dense food and drinks) and increased physical activity. No pharmacological agents will be provided or promoted.

The general educational components of healthy eating and active living will initially be explained using the British Heart Foundation (2010) booklet “So you want to lose weight for good” (which includes the Food Standards Agency “Eatwell” plate model (the national food guide) [28]. Portion guidance and information on energy dense food and drinks (highlighting fast foods and sugary drinks) will be provided with reference to the information in the BHF guide. With respect to physical activity, demonstrations will be given on “brisk walking” and a pedometer provided for self-monitoring. The translation of 7% weight loss will be provided as a personal weight loss target for the 12 month period. This will include guidance on a personalised minus 600 kcal energy deficit diet (based on estimated Basal Metabolic Rate), provided on the basis of food group portion sizes and portion frequencies. Options on following this completely (e.g. starting on minus 600 kcals) from day 1 or building up to minus 600kcals will be discussed with reference to the weight loss requirements over a 12 month period.

Motivational interviewing [29] will be utilised to explore self-assessed confidence, ambivalence and personal values concerning weight change. A 24-hour recall of dietary intake will be taken to promote discussion around current diet and allow counsellors to introduce the concept of personalised dietary change. Study participants will have worn a SenseWear Pro_3 physical activity monitor (Body Media Inc.) for seven days to provide

baseline physical activity records (also worn by the usual care group), prior to being visited by the lifestyle counsellor. The output from the monitors will be utilised to provide feedback on current activities and to promote discussion around opportunities to increase leisure time activity where possible.

To assist change in both diet and physical activity, participants will be encouraged to focus on one topic (diet or physical activity) for the remainder of visit one, and the remaining topic on visit two, generally advising that the strongest area of existing success is likely to be the best to begin with. To aid improvements in self- efficacy, participants will be encouraged to identify specific behavioural goals [30] and make short term specific implementation intentions [31]. Success or failure with these goals will be discussed at follow up visits. Self-monitoring will also be encouraged and participants will be presented with body weight scales for weekly weighing, pedometers to monitor daily step counts, and log books. A number of behavioural and re-enforcement techniques will be employed in this part of the counselling session including tool kits to assist change, practical discussions on food preparation (or equipment demonstrations) and self-recording sheets for the specific implementation intentions identified. Tool-kits will include items for loan including kitchen gadgets such as salad spinners and hand blenders, and physical activity tools such as steppers, hand weights, hula hoops, exercise DVDs and walking poles. In addition, to encourage loyalty to the study all participants will be given tools with the BeWEL logo: a water bottle to reinforce the message to reduce sugary drink intake, and a fabric bag for transporting scales home and/or to act as reminder for healthy eating while shopping.

The first session will finish with a return to weight matters, and instructions for self-monitoring and recording of weight will be given. Contact details for professional support will be provided and the next appointment made. Visits 2 and 3 will have similar formats, checking well-being discussing and providing feedback on progress and experiences, exploring areas of difficulty and providing encouragement. Visit 2 will also encourage a focus on the second topic area (diet or activity) not selected in visit 1. The content of all visits is presented in table 1.

By the end of visit 3, all participants will have identified a specific set of personalised diet and activity implementation intentions and weight loss goals for the remainder of the study.

The remainder of the intervention will be delivered by telephone (Table 2). Nine further telephone calls from three to twelve months will be completed before participants return to the research centre for follow up measures. LCs will continue to support BeWEL participants in their attempts to lose the target 7% body weight. Participants who do achieve this target but who remain overweight will be encouraged to continue the weight loss

programme. Participants who have met their target weight loss (and are no longer overweight) will be encouraged to adopt a weight maintenance approach.

Follow up calls will begin with a general introduction about mental and physical well-being and LC's will attempt to elicit participant's views on making lifestyle change. LC's will be responsible for checking participant's progress since visit 3 and the first follow up at three months, discussing areas of success and difficulty. LC's will provide the participant with further verbal (and where appropriate written) and personalised lifestyle advice to promote optimal dietary intake, physical activity and weight loss. Personalised goals will be agreed and updated through discussion with the participant and the LC's will keep records of these to provide personalised feedback and continuity through to follow up at twelve months.

Protocol adherence and monitoring

Lifestyle counsellors will keep participant notes recording the application of the above procedures and these will be reported to the study team as an indirect check on intervention fidelity and to encourage protocol adherence. Regular meetings will be held with all counsellors to discuss challenges in protocol adherence and possible solutions to address problems, which will be re-assessed at follow up workshops. A protocol minor amendment has also enabled approval to be given for research team members to be present at face-to-face intervention sessions and to record telephone counselling.

Programme acceptability will be explored post-intervention with in-depth exit interviews (undertaken by staff not involved with programme delivery) with a random sample of 30 intervention participants. Interviews will cover participants' initial expectations and motivations regarding the programme, the extent to which these were met or not by their subsequent experiences, and factors influencing their ability to make the recommended lifestyle changes [14]. A thematic analysis of interview transcripts will be undertaken, exploring such themes as what factors influence decisions to engage in the programme, how uptake is influenced by socio-economic status, the practical barriers and opportunities for facilitating physical activities and changes in dietary habits, and the perceived acceptability of the programme to participants and families.

The impact of specific component parts on outcomes will not be assessed, but reported compliance with diet and physical activity goals will be available from post intervention measures [14]

Ethics and Dissemination

Ethical approval for the intervention content was obtained from the Tayside Committee on Medical Research Ethics.

Financial support is provided by the National Prevention Research Initiative (NPRI) (http://www.npri.org.uk), grant award number G0802030. NPRI is a national research initiative administered by the Medical research Council (MRC) made up of the following funding partners: Alzheimer's Research Trust; Alzheimer's Society; Biotechnology and Biological Sciences Research Council; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Engineering and Physical Sciences Research Council; Health & Social Care Research & Development Office for Northern Ireland; Medical Research Council; Welsh Assembly Government; and World Cancer Research Fund. In addition, further financial support is also being provided by the NHS Research Scotland (NRS), to carry out this work. The study is sponsored by the University of Dundee.

Governance for the study is provided by a Trial Steering Committee (TSC) with an independent Chairperson, representatives from other academic institutions, non–governmental organisations (NGO), patient representatives and representatives from the sponsor and funding agency. However, decisions on study design, protocol amendments, data collection, management, analysis and data interpretation, publication policy and report writing and submission are made by the Trial Management Committee (TMC) subject to approval by TSC aided by an independent Data Monitoring and Ethics Committee (DMEC) .

The detailed intervention protocol provides a standardised approach to intervention design, delivery and content for use in diet, physical activity and weight loss trials. The rationale for the total amount of contact time (5.25 hours over a 12 month period) with counsellors would be similar to monthly weight management appointments in NHS (primary care) but less than commercial slimming clubs. Minimal contact enables costs to be minimised but professional support to be retained.

Group work was not considered because of the geographical spread of the regions in which the trial is being carried out, and the subject face-to-face time burden. Minimal contact approaches such as phone and email have been shown to produce promising results for weight loss with high frequency calls from a health professional producing similar results to high frequency face-to-face lifestyle modification counselling [32-33]

The content of the intervention was based on current guidelines for weight management from the Scottish Intercollegiate Guidelines Network [34] which recommends a combination of physical activity, diet and behavioural therapy components. The behavioural strategies used draw on evidence for successful dietary changes from Ammerman et al [35] and weight loss management from the National Institute for Health and Clinical Excellence [36].

The fidelity of the intervention content and delivery will inevitably vary by the individual style of each lifestyle counsellor but training sessions have emphasised the need to deliver all components but modify to suit the participants' individual circumstances e.g. disability, economic circumstances or learning difficulties. Whilst family/friend support is recommended it is recognised that this will not be possible to access in all cases.

The ease of undertaking all contacts with participants, delivering the intervention components and feedback from participants will provide insight to the practical acceptability of this theory based, practice focussed intervention design.

The dissemination of the trial findings will principally be carried out through publications in peer reviewed journals, presentations at national/international cancer focussed meetings and to NHS groups including the Scottish Cancer Task Force. In addition the work will be communicated to the public through forums such at The Scottish Cancer Prevention Network (http://www.cancerpreventionscotland.co.uk/)

Trial registration

The trial is registered with Current Controlled Trials (International Standard Randomised Controlled Trials No: ISRCTN53033856).

List of abbreviations

CRC: Colorectal cancer

T2DM: Type 2 diabetes mellitus

CVD: Cardiovascular disease

WCRF: World Cancer Research Fund

LCs: Lifestyle Counsellors

Competing interests

The authors declare that they have no competing interests.

Authors contributions

SC has prepared materials for intervention inclusion, advised on implementation strategies and drafted manuscript,

AC has advised on physical activity measures and tools, overall package design and manuscript drafting

JW has contributed advice on behavioural techniques, educational strategies and overall design components

MS has contributed to specific translation details from formative work into overall intervention, focussing on educational material and all communications

ASA Is Principal investigator for the study and has over seen the intervention design, development and implementation and manuscripts drafting and editing

All authors have contributed to intervention design, study design, final protocol and manuscript editing

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Table 1- Delivery and Content of Counsellor visits (contacts 1-3)

	Visit 1	Visit 2	Visit 3
Contact	Face-to-face	Face-to-face	Face-to-face
Time line	Following baseline assessment	Week 6-8	Three months
Duration	90 mins	45 mins	45 mins
Who Delivers	Trained Counsellor	Trained Counsellor	Trained Counsellor
Intervention location	Home/Research Centre	Home/Research Centre	Home/Research Centre
Social support	Invited friend / partner/family member	Invited friend / partner / family member	Invited friend / partner / family member
Introduction	Check nurse assessment • Importance of lifestyle change • Consultant endorsement • Identify 12 month weight loss target	• Current well-being • Experience of making change • Importance of modest change • Building towards 12 month weight loss target	• Current well-being • Experience of making change • Importance of modest change • Building towards 12 month weight loss target
Motivational approaches	24 hour dietary recall / activity assessment • Identify perceived diet/activity challenges • Identify self-assessed motivations, confidence, ambivalence and personal value regarding weight change	Identify Self monitored weight • Provide feedback • Provide encouragement • Identify self- assessed motivations, confidence, ambivalence and personal values re change	Identify Self monitored weight • Provide feedback • Provide encouragement • Identify confidence and support needs
Education - General	Healthy Eating and Activity Principles • Portion size • Energy dense food and drinks • Breakfast meals and snacks • Activity and Inactivity	Discuss experience of changing diet and activity referring back to perceived challenges at visit 1. Check for queries , or areas of confusion or elaboration	Discuss experience of changing diet and activity referring back to perceived challenges at visit 1 and 2 Check for queries , or areas of confusion or elaboration

	Visit 1	Visit 2	Visit 3
	Demonstration of brisk walking +pedometer	Discuss walking + pedometer	Discuss walking + pedometer
Education – Personalised	Structured weight loss programme minus 600kcal diet prescription plan	Discuss progress towards achieving minus 600 kcals diet	Discuss progress towards achieving minus 600 kcals diet
Behavioural and re-enforcement techniques **DIET or ACTIVITY**	Introduce Diet or Activity focus 1	Discuss self-monitoring of focus 1 Provide positive feedback Identify challenges Discuss maintenance Introduce Diet or Activity focus 2	Discuss self-monitoring of focus 2 Provide positive feedback Identify challenges Discuss maintenance of focus 1 and 2 Negotiate key long term diet and activity goals based on: Perceived achievements Summarise success
Behavioural and re-enforcement techniques **WT MANAGEMENT**	Provide body weight scales Explanation of self-monitoring procedures Remind about 12month goal	Re-enforce body weight techniques	Check body weight scales and the need for continued monitoring
Professional support	Provide tel and email contact details Identify next 2 appointments	Confirm next appointment and identify date for call 1	Confirm call 1 and identify date for call 2

Table 2 Telephone intervention for contacts 4-12

	Contacts 4-12
Contact	Telephone
Time line	Following on from 3rd face-to-face contact until 12 month follow up assessment.
Duration	10-15 mins
Who Delivers	Trained Counsellor
Introduction	General exchange about mental and physical health Elicit participant's overview on progress and change made Re-enforce importance of modest behaviour change for health benefit Importance of change and building towards 12 month weight loss target. 3 months gone but 9 months to continue improvement.
Motivational approaches	Check self-monitoring records Identify perceived diet/activity challenges Identify self-assessed motivations, confidence, ambivalence and personal value re weight change
Informing Change	Re-enforce portion size guidance/energy dense foods/energy dense drinks Importance of remaining active
Personal Goals (implementation intentions)	Continue to focus on short term implementation intentions and review these at next call.
Setting long term goals	Identify perceived achievements and summarise success Re-evaluate confidence, motivation and importance of changes made
Professional support	Make appointment for next telephone call but re-iterate you can respond to questions before this call as they arise.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 3
	2b	Specific objectives or hypotheses	Page 4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	Page 4
	4b	Settings and locations where the data were collected	Page 4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 14 and 15
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Described elsewhere see page 3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	Described elsewhere see page 3
	7b	When applicable, explanation of any interim analyses and stopping guidelines	DMC reported elsewhere see page 3
Randomisation:			Described elsewhere see page 3
Sequence	8a	Method used to generate the random allocation sequence	

generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Described elsewhere see page 3
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	Described elsewhere see page 3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	statistician
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Described elsewhere see page 3
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Described elsewhere see page 3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Described elsewhere see page 3
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Will be reported elsewhere
	13b	For each group, losses and exclusions after randomisation, together with reasons	Will be reported elsewhere /a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Will be reported elsewhere
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Will be reported elsewhere
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	Will be

		by original assigned groups	reported elsewhere
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Will be reported elsewhere
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Will be reported elsewhere
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	SAE's are being recorded
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Will be reported elsewhere
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Will be reported elsewhere
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Will be reported elsewhere
Other information			
Registration	23	Registration number and name of trial registry	Page 2
Protocol	24	Where the full trial protocol can be accessed, if available	Page 3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 9

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 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.