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The feasibility of a peer support intervention to encourage adoption and maintenance of a Mediterranean diet in established community groups at increased CVD risk: the TEAM-MED EXTEND study: a pilot cluster randomised controlled trial

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Abstract

This study aimed to evaluate the feasibility of a peer support intervention to encourage adoption and maintenance of a Mediterranean diet (MD) in *established* community groups where existing social support may assist the behaviour change process. Four established community groups with members at increased Cardiovascular Disease (CVD) risk and homogenous in gender were recruited and randomised to receive either a 12-month Peer Support (PS) intervention (PSG) (*n* 2) or a Minimal Support intervention (educational materials only) (MSG) (*n* 2). The feasibility of the intervention was assessed using recruitment and retention rates, assessing the variability of outcome measures (primary outcome: adoption of an MD at 6 months (using a Mediterranean Diet Score (MDS)) and process evaluation measures including qualitative interviews. Recruitment rates for community groups (*n* 4/8), participants (*n* 31/51) and peer supporters (*n* 6/14) were 50 %, 61 % and 43 %, respectively. The recruitment strategy faced several challenges with recruitment and retention of participants, leading to a smaller sample than intended. At 12 months, a 65 % and 76·5 % retention rate for PSG and MSG participants was observed, respectively. A > 2-point increase in MDS was observed in both the PSG and the MSG at 6 months, maintained at 12 months. An increase in MD adherence was evident in both groups during follow-up; however, the challenges faced in recruitment and retention suggest a definitive study of the peer support intervention using current methods is not feasible and refinement based on the current feasibility study should be incorporated. Lessons learned during the implementation of this intervention will help inform future interventions in this area.

Key words: **Mediterranean diet: Peer Support: Cardiovascular risk: Community-based intervention**

Epidemiological evidence suggests that adherence to a Mediterranean diet (MD) is associated with a reduction in the risk of Cardiovascular Disease (CVD), Type 2 Diabetes and Metabolic Syndrome[1–4]; a systematic review – pooling available cohort studies – suggests a 10 % (relative risk = 0·90; 95 % CI 0·87, 0·92) reduction in CVD risk[1] and a 10 % (relative risk = 0·90; (95 % CI 0·89, 0·91) reduction in overall mortality per two-point increase in an MD adherence score[4]. The exact mechanism for this reduction in disease risk is unknown; however, adherence to an MD is associated with improvements in risk factors for both CVD and diabetes, including blood pressure, lipids, biomarkers of inflammation and insulin resistance[5,6]. Experimental research supports these findings: in a population at increased risk of CVD, the *Prevención con Dieta Mediterránea* trial demonstrated that adoption of an MD led to an approximate 35 % (hazard ratio 0·65; 95 % CI 0·50, 0·85) reduction in CVD incidence and a 52 % (hazard ratio 0·48 (95 % CI 0·27, 0·86)) reduction in Type 2 Diabetes within the MD intervention arm (supplemented with nuts or extra virgin olive oil) compared with the low-fat diet control arm[7,8].

Within such interventions, intensive methods – usually delivered by healthcare professionals – were required to encourage dietary behaviour change commensurate with an MD[7–10]. Such strategies are not practical or cost effective when

Abbreviations: CVD, Cardiovascular disease; MD, Mediterranean diet; MSG, Minimum Support Group; NI, Northern Ireland; PSG, Peer Support Group; PSR, Peer Supporter.

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considering a population-level approach to behaviour change; however, peer support offers a potential alternative and less costly approach[11,12]. Peer support may encourage behaviour change via the utilisation of social support and social networks between individuals; a peer supporter (PSR) is an individual with similar characteristics to the target population *'who possesses experiential knowledge of a specific behaviour or stressor'* and can provide '*emotional, appraisal, and informational assistance to address a health-related issue*'[13]. Many peer support approaches exist, including face-to-face, online, telephone and individual peer coaching[14,15]; however, qualitative research suggests that a group-based peer support approach is the preferred method to encourage a population at high risk of CVD towards adoption of an MD[16].

The Trial to Encourage Adoption and Maintenance of a Mediterranean Diet

This intervention was designed by our research team to test a group-based peer support programme and compare it with a proven intensive dietitian-led MD intervention and a minimal MD education intervention for encouraging adoption of the MD in adults at high CVD risk in Northern Ireland (NI)[17]. Due to the individual level randomisation process, study participants within the peer support intervention arm were recruited and randomised independently, resulting in newly established groups with individuals varying by characteristics such as age, gender and socioeconomic status. This individual-level randomisation also led to a delay in initiation of the intervention, which did not begin until enough participants had been randomised to the peer support intervention, to allow the formation of a group[17].

Research suggests that already established groups may have greater social cohesion and engagement compared with members in newly formed groups and the leveraging of existing social networks between members may enhance the effectiveness of peer support strategies to further encourage behaviour change[16,18,19]. This is supported by published qualitative data in individuals at increased risk of CVD which suggests that effective peer support groups develop from individuals who consider each other '*similar*' and can develop trust and honesty within their groups[16]. This led the research team to consider the effect of the TEAM-MED intervention in already established groups leading to the design of the TEAM-MED EXTEND feasibility study.

TEAM-MED EXTEND. The aim of this study was to determine the feasibility of the TEAM-MED peer support intervention to encourage adoption and maintenance of an MD[17], in *established* community groups, in comparison with a less intensive MD minimal education intervention (control). This paper provides an overview of the study design, implementation strategy and outcomes assessed including the adoption of an MD (assessed by a change in MDS at 6 months from baseline (adoption) and change in MDS at 12 months from 6 months (maintenance)). We consider the challenges faced in implementation and adoption of this intervention in an *established* community group setting and consider the modifications necessary for the development of future group-based peer support interventions in populations at risk of CVD.

Methods

Study design

This pilot study employed a Cluster Randomised Controlled Trial design over a 12-month study period and was conducted according to the guidelines laid down in the Declaration of Helsinki. All procedures involving human participants were approved by the Research Ethics Committee for the School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast (Ref: 15·25.v5) and the trial also conforms to the Consolidating Standards of Reporting Trials statement's[20] extension to randomised pilot and feasibility trials[21] – a checklist is included in the appendices.

Eligibility and recruitment

Recruitment was completed between January and June 2016. The recruitment strategy employed a similar approach to the original TEAM-MED study, which included the dissemination of email and media releases to community organisations through local community links in NI[17].

An '*established*' community group was defined as a group or network drawn from one community, containing regular service users and if possible homogenous sex. Interested groups contacted the research team to arrange for further information and a researcher attended to provide participant information sheets and a comprehensive overview of the study to community group members. Researchers then returned to screen individual group members and determine eligibility for groups and participants wishing to proceed. The individual screening process included a personal health and medical history questionnaire to determine CVD risk and a fourteen-item MDS questionnaire – to determine the baseline adherence to an MD. This is similar to the MD score used in the *Prevención con Dieta Mediterránea* study[8] but has been modified to reflect the diet of an NI population[17].

We intended that 75 % of community group members drawn from a given group (for example: a Men's Shed or a Women's Group) should be eligible in order for the overall group to be eligible to participate, with a target of recruiting 10–12 eligible participants per community group. Ineligible group members were welcome to participate in PS sessions if their community group was randomised to the Peer Support Group (PSG), but these individuals had no further contact with the research team post screening.

Inclusion & exclusion criteria – individual screening

Both peer supporters (described below) and community group members were eligible to participate if they were (a) aged ≥ 40 years; (b) had a Mediterranean Diet Score (MDS) ≤ 3 and (c) had at least one CVD risk factor as detailed in Table 1. The exclusion criteria included (a) a diagnosis of Diabetes Mellitus (excluded only if receiving oral medication or insulin treatment), (b) established CVD, (c) any medical conditions or dietary restrictions that

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Table 1. Study inclusion and exclusion criteria for community groups, group members and peer supporters

Inclusion criteria
Community groups
• Drawn from one community network/centre
• Made up of regular service users
• Homogeneous sex
Group Members
• Aged ≥ 40 years
• Have a Mediterranean Diet Score (MDS) ≤ 5*
• Have at least one of the following Cardiovascular Disease (CVD) risk factors:
– Type 2 Diabetes Mellitus and NOT on any medication (oral or insulin; if receiving treatment then excluded)
– Smoker (current)
– Hypertension (high blood pressure (BP)) systolic BP ≥ 140 or diastolic ≥ 90 mmHg
– On anti-hypertensive medication
– Elevated Low Density Lipoprotein (LDL)-cholesterol ≥ 160 mg/dl
– Low High Density Lipoprotein (HDL)-cholesterol ≤ 40 mg/dl (men) – ≤ 50 mg/dl (women) (milligrams per deciliter of blood)
– On cholesterol-lowering medication
– Overweight OR obesity (Body Mass Index (BMI) > 25)
– Family history of premature Coronary Heart Disease (CHD) (definite Myocardial Infarction (MI) or sudden death before age 55 in male father or first-degree relative or before 65 in mother of first-degree relative (e.g. parent, sibling or child)
– Ethnicity (South Asian (Afghanistan, India, Pakistan, Bangladesh, Sri Lanka, Nepal, Bhutan and Maldives); or African Caribbean).
Peer Supporters (in addition to criteria for group members)
– A lay participant or community health worker/volunteer
– A commitment to completing peer supporter training and delivery of the intervention over a 12-month period
Exclusion criteria (community groups, participants and peer supporters)
• Diabetes mellitus (excluded only if receiving oral medication or insulin treatment)
• Established CVD
• Medical conditions or dietary restrictions that would substantially limit ability to complete the study requirements
• Inability to provide informed consent
• Community groups led by health professionals

* Modified from an initial requirement of an MDS score ≤ 3.

would substantially limit ability to complete the study requirements, (d) inability to provide informed consent and (e) community groups led by health professionals. A detailed overview of the inclusion and exclusion criteria for this two-phase recruitment process is presented in Table 1. Written informed consent was obtained from all eligible individuals agreeing to participate in the study.

Recruitment and training of peer supporters

This is discussed in detail elsewhere[17]. Briefly, recruitment of PSR was completed separately to community group recruitment via the dissemination of a poster advertisement to community organisations and networks in NI. The screening process for PSR was similar to that of the community group participants (discussed above); however, eligible PSR also completed an interview (by the research team) to determine their commitment to participate and to identify if they had the attributes desirable for the PSR role; the peer supporters were not familiar with their allocated community group at the outset of the study, and this interview was used to facilitate the pairing of PSR to the most suitable community group, ensuring – as much as possible – that the PSR had similar characteristics to their allocated community groups, increasing the likelihood that they would be welcomed as peers by the community groups. The training provided was identical to that delivered in the previous intervention[17]. Two PSR were allocated per community group randomised to the intervention; where possible, one had experienced success in making positive changes to their diet and the other was familiar with group facilitation. Two additional PSR were recruited to act as reserves for either group if required.

Randomisation

Post-screening, eligible community groups were randomly allocated to either the PSG or a Minimum Support Group (MSG) (control) using a computer-based random allocation sequence generator (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24·0. IBM Corp), which was performed by an independent member of the research team not involved in the screening or data collection process. The Centre/Project manager was informed of group assignment, and study participants were informed individually after their baseline measurements were completed.

Peer Support Intervention

The intervention was developed using the Medical Research Council's guidance for developing complex interventions[22] and is based on the social support model in healthcare[13,23]; this has been described in detail elsewhere[17]. Explicit Behaviour Change Techniques incorporated into the intervention included social support, goal-setting, self-monitoring and problem-solving[24,25]. The intervention consisted of eleven ~2-h peer support sessions, conducted within the usual community group venue, designed to be interactive and non-directive with a focus on discussion and the sharing of experiences between the PSR and the group: these sessions were delivered at week 0 (baseline), week 2, week 4, week 6 and month 2, month 3, month 4 and month 6

during an initial intense phase and then months 8, 10 and 12 during the latter maintenance phase[17]. All sessions began with an MD educational component delivered by the PSR and topics covered included: 'Health benefits of a MD', 'Enjoying Fruit & Vegetables', 'Eating more Wholegrain', 'Eating a Seasonal MD' & 'Shopping for a MD'. Practical demonstrations including tasting sessions of MD foods and dishes were incorporated throughout the intervention (during *n* 4 of the 11 sessions). Each participant was provided with a range of MD educational resources including written educational materials providing information on the MD, the health benefits of an MD and practical support to facilitate adoption of this dietary pattern including recipe books, shopping lists and meal plans. A workbook to facilitate goal setting and self-monitoring throughout the intervention was also provided to participants. PSR were trained to encourage participants to set Specific, Measureable, Achievable, Realistic & Time-based (SMART) goals at each intervention session[26,27].

Minimum Support Group

Participants within the community groups randomised to the MSG arm (*n* 2) received written educational literature, developed by the research team for the TEAM-MED study[17] on the food components of the MD, seasonal recipe ideas, meal plans and shopping lists after their baseline visit. MSG participants received no further input, only follow-up data collection visits at 3, 6 and 12 months.

Study evaluation

The feasibility of the intervention was assessed using recruitment and retention rates, participant engagement (via attendance records of PS sessions), end-of-study evaluation measures (designed for the TEAM-MED intervention and including MD tolerance and group cohesion questionnaires (PSG only)). We also invited all participants randomised to the PSG – as well as the PSR – to complete a post intervention structured interview at study endpoint to assist in our process evaluation. These were completed either in-person (on a one-to-one basis) at the end of the final measurement visit or by phone within a week of the final visit if more convenient for the participant and took approximately 20 min to complete. Intervention fidelity was determined by (1) the standardisation of intervention delivery with a two-day training course provided to all PSR at the start of the study; (2) structured post-session phone calls with each PSR to offer support and answer questions in an effort to minimising drift in skills and knowledge acquired during the training course; (3) the observation (by a member of the research team) of three intervention sessions to ensure the monitoring of intervention delivery and consistent implementation across and between intervention groups and (4) attendance recorded at each session to determine the engagement of each group participant to the intervention.

Outcome assessment

Outcome measurements were collected to explore the variability of outcomes to inform a larger study and test the acceptability of the measurement tools used. The primary outcome of interest was adoption of an MD assessed by a change in MDS at 6 months from baseline (adoption) with change in MDS at 12 months from 6 months (maintenance) as a secondary outcome. MDS were determined using a fourteen-item questionnaire, similar to that used in the *Prevención con Dieta Mediterránea* study[8] but modified for an NI population[17]. The MDS used in this study has been validated with MDS from previous studies[1,10,28] and has demonstrated moderate agreement between this tool and the score used in the *Prevención con Dieta Mediterránea* study thus providing a potentially valid tool for determining MD adherence in a Northern European population. Secondary outcomes included changes in nutrition and health markers at follow-up from baseline, including anthropometry – weight (to the nearest 0·1 kg using Tanita HS-301 calibrated scales) and height (to the nearest 0·1 cm using a portable Stadiometer), both of which were used to calculate BMI (kg/m^2), waist and hip circumference measurements (using a flexible tape measure to the nearest 0·1 cm), blood pressure (using a calibrated automated sphygmomanometer (Omron M5–1, OMRON Healthcare UK Ltd., Milton Keynes, UK)), dietary intake (4-d estimated food diary) and MD Knowledge using an MD Knowledge questionnaire[29]. Spot non-fasting urine and saliva samples (Greiner Bio-One Saliva Collection System) were collected at each time point for the future analysis of objective measures of nutritional status and CVD-related biomarkers. Physical activity levels were also determined using the General Practice Physical Activity Questionnaire[30]. A social support questionnaire – based on a modified version of the validated UCLA social support inventory was used to collect information on the sources of support available to participants[9]. Psychosocial measurements including health[31] and dietary[32] related quality of life, mood[33], self-efficacy[34] and self-esteem[35] were also collected (Table 2). A brief item assessing oral difficulties and frequency of dental visits[36,37] was used to assess dental health at baseline and endpoint only. An overview of study outcomes, measures used and the time point of assessment is summarised in Table 2. The duration of each follow-up visit was approximately 2 h; these were completed in a private room within the local community centre participating in the study. If participants were restricted for time, the physical measurements and the assessments relating to adoption of the MD (including the MDS score, review of the food diary and MD knowledge questionnaire) were prioritised during the in-person appointment, and participants were provided with a stamped addressed envelope and asked to complete the remaining questionnaires at home, posting these back to the study team within a week of their study measurement appointment.

Statistical analysis

A sample size calculation for this study was not appropriate, as the pilot data generated here will be used to inform the development of a large-scale trial and any changes in outcome data were exploratory only. For community groups, the recruitment rate is calculated based on those consenting to study screening compared with the total number of groups requesting study information. Individual recruitment is calculated as those eligible and consenting to participant compared with the total number of individuals requesting information and/or screened for eligibility (within the included community groups only). The recruitment

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Table 2. Outcome and evaluation measures used at each study time point

Outcome	Domain to be measured	Data collection method (s)	BL	3 months	6 months	12 months
Diet	MD adherence	14-item MDS questionnaire*[8]	✓	✓	✓	✓
	Dietary intake	Food record (4 day)	✓	✓	✓	✓
Clinical & biomarkers	Blood pressure	Clinically measured – (omron M5–1 healthcare)	✓	✓	✓	✓
	Weight	Digital scales	✓	✓	✓	✓
	Height	Stadiometer	✓	✓	✓	✓
	Waist circumference	Flexible tape	✓	✓	✓	✓
	Nutrition and CVD markers	Urine (spot fasting sample) Saliva (Greiner bio-one saliva collection system)	✓	✓	✓	✓
Mediators of diet behaviour change	MD knowledge	Nutrition knowledge questionnaire*[29]	✓	✓	✓	✓
	Readiness to change behaviour	Stage of dietary change questionnaire†[51]	✓	✓	✓	✓
	Perceived barriers to MD	Eating habits questionnaire†	✓	✓	✓	✓
	Self-efficacy	Questionnaire[34]	✓	✓	✓	✓
	Social support	Questionnaire[52]	✓	×	✓	✓
	Problem solving ability	Questionnaire*[9]				
Intervention Moderators	Physical activity	GPPAQ[30]	✓	✓	✓	✓
	Smoking, alcohol, medication use	Questionnaire†	✓	✓	✓	✓
	Health beliefs	Health Beliefs Questionnaire*[53]	✓	×	×	✓
	Health related QoL	SF-36[31]	✓	×	×	✓
	Diet-related QoL	Questionnaire[32]	✓	×	×	✓
	Mood	Questionnaire[33]	✓	×	×	✓
	Self-esteem	Self-esteem Questionnaire[35]	✓	×	✓	×
	Oral health	Questionnaire[36,37]	✓	×	×	✓
Process Evaluation Measures	MD Tolerance	Questionnaire†	×	×	×	✓
	Group cohesion	Questionnaire†	×	×	✓	✓
	Study evaluation	Questionnaire†	×	×	×	✓

BL, baseline; MD, Mediterranean Diet; GPPAQ, General Practice Physical Activity Questionnaire.
This table is adapted from the original TEAM-MED protocol paper[17].
* Modified for TEAM-MED.
† Developed for TEAM-MED intervention.

rate for PSR is based on those completing PSG training compared with all individuals requesting information on the PSR role. Retention rates were calculated based on the number of participants completing measurements at each time point compared with the total number consenting to participate at baseline.

Baseline descriptive information on a range of demographic and health-related characteristics – by individual community group and by randomisation group (PSG and MSG) – are presented (Table 3). Descriptive statistics – including means and standard deviations for parametric data, medians and inter quartile range for non-parametric data – are presented for the primary and secondary outcomes across follow-up time points but inferential statistics were not completed. All quantitative analyses were conducted using the Statistical Package for Social Sciences (SPSS) (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. IBM Corp). The end-of-study interviews were recorded and transcribed verbatim and then coded by two members of the research team and analysed within a thematic framework following the steps outlined by Braun and Clark[38].

Results

Study recruitment and modifications to eligibility criteria

An overview of study recruitment and retention across the follow-up time points is presented in Fig. 1. We faced several challenges in the early phase of recruitment for several reasons including a lack of interest and concerns regarding the time commitment involved in participation (justifications made during informal discussions with the centre/project managers of the groups deciding not to complete screening), or ineligibility – with interested participants not meeting the group criteria and/or the individual screening criteria. To address this, the study team modified the eligibility criteria, making these less stringent to encourage a broader sample for inclusion. The following changes were made to the eligibility criteria to overcome low recruitment rates:

(1) The target for 75 % of individual members of groups to be eligible in order for the group to participate was reduced to 50 % of the overall group.
(2) The MDS screening criterion for inclusion was increased from ≤ 3 to ≤ 5.

Ten community organisations contacted researchers requesting further information and *n* 8 consented to study screening – an 80 % recruitment rate, of which half (*n* 4) met the eligibility criteria: *n* 3 were female only groups and *n* 1 male only group. Eight of fourteen interested PSR received training (57 %) with six recruited to the role (43 %). Seven of the *n* 8 peer supporters trained for the role were female (87·5 %).

Thirty-one of *n* 51 individual members across the four community groups met the eligibility criteria and consented to participate in the study (61 %); *n* 9 of all participants were male

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Table 3. Baseline characteristics of participants by allocated intervention group

	Peer Support Group (PSG)						Minimal Support Group (MSG)					
	Total (*n* 14)		PSG1 (*n* 9)		PSG2 (*n* 5)		Total (*n* 17)		MSG1 (*n* 9)		MSG2 (*n* 8)	
Variable	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Age (years)												
Mean	54·6		51·8		59·6		63·5		67·1		59·5	
SD	8·7		7·3		9·5		12·1		8·8		14·6	
Sex %(*n*)												
Females	100·0	14	100·0	9	100·0	5	47·0	8	0·0	0	100·0	8
Males	0·0	0	0·0	0	0·0	0	53·0	9	100·0	9	0·0	0
Education (years)	12·0	3·0	12·0	2·0	11·0	2·0	13·0	3·0	11·0	2·0	14·0	1·0
Smoking Status % (*n*)												
Current	14·3	2	22·2	2	0·0	0	11·8	2	22·2	2	0·0	0
Previous*												
Median	25·0		28·6		20·0		33·3		57·0		12·5	
IQR	3		2		1		5		4		1	
Alcohol (units)												
None/Occasional	71·4	10	66·7	6	80·0	4	47·1	8	33·3	3	62·5	5
1–2	21·4	3	22·2	2	20·0	1	17·6	3	0·0	0	37·5	3
3–5	7·1	1	11·1	1	0·0	0	29·4	5	55·6	5	0·0	0
6–7	0·0	0	0·0	0	0·0	0	5·9	1	11·1	1	0·0	0
Marital Status % (*n*)												
Married/Cohabitating	28·6	4	44·4	4	0·0	0	76·5	13	77·8	7	75	6
Single†	71·4	10	55·6	5	100	5	23·5	4	22·2	2	25	2
Antihypertensive Meds % (*n*)	28·6	4	33·3	3	20	1	41·2	7	44·4	4	37·5	3
Lipid-lowering medication % (*n*)	7·1	1	11·1	1	0·0	0	29·4	5	33·3	3	25·0	2
Supplement % (*n*)	35·7	5	22·2	2	60·0	3	17·6	3	11·1	1	25·0	2
Stage of change % (*n*)												
Pre-contemplation	7·1	1	11·1	1	0·0	0	5·9	1	11·1	1	0·0	0
Preparation	78·6	11	66·7	6	100	5	58·8	10	55·6	5	62·5	5
Contemplation	14·3	2	22·2	2	0·0	0	35·3	6	33·3	3	37·5	3
Height (m)												
Mean	1·6		1·6		1·6		1·7		1·7		1·6	
SD	0·6		0·6		0·7		0·6		0·6		0·5	
Weight (kg)*												
Median	79·6		79·7		79·5		71·0		81·7		68·4	
IQR	21·2		16·3		14·7		14·6		19·6		5·9	
BMI (kg/m^2)*												
Median	31·1		31·2		31·1		26·1		29·1		25·3	
IQR	3·9		3·3		2·9		4·3		3·9		2·9	
WC (cm)												
Mean	103·1		103·0		102·0		94·8		99·2		89·7	
SD	12·1		12·0		13·9		9·8		8·5		8·9	
HC (cm)*												
Median	107·3		108		106·5		104·2		104·3		103·4	
IQR	13·3		13·3		9·0		5·2		4·8		6·4	

	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
WHR	0·92	0·09	0·90	0·07	0·96	0·12	0·91	0·07	0·95	0·06	0·86	0·06
Systolic BP (mmHg)	126·0	12·7	126·0	8·7	128·0	18·8	128·0	20·0	134·0	20·7	122·0	8·7
Diastolic BP (mmHg)	85·0	9·8	88·1	8·2	79·4	10·9	77·2	8·7	79·9	10·6	74·2	5·1
MDS Score	3·2	1·8	2·9	2·0	3·8	1·3	3·4	1·3	3·7	1·1	3·0	1·5

WC, waist circumference; HC, hip circumference; WHR, waist:hip ratio; MDS, Mediterranean Diet Score.
* Median (IQR) for non-parametric data.
† Also includes those separated or divorced.

(29 %). Reasons for ineligibility of group participants at screening included an MDS score > 5, a low CVD risk after screening and/or participation in a commercial weight loss programme. The sizes of the four groups ranged from *n* 5–9 participants – less than the target of 10–12 participants per group – notably due to either ineligibility after screening or a lack of interest due to the time commitment involved in participation. Fourteen participants (one group of *n* 5 and another of *n* 9 participants) were randomised to receive the PSG intervention and *n* 17 (a group of *n* 9 and another of *n* 8) were randomised to the MSG.

Study retention

At both 6 and 12 months, the retention rate was 64 % (9/14) within the PSG arm and 76·5 % (13/17) within the MSG arm. The reasons provided for study drop-out by participants within the PSG arm included relocation (*n* 2), not contactable (*n* 1), no-show (*n* 1) and conflicting advice from a commercial weight loss programme regarding fat intake (*n* 1) – despite this being an exclusion criterion for participation. Within the MSG group, reasons included: work/family commitments (*n* 2), the burden of

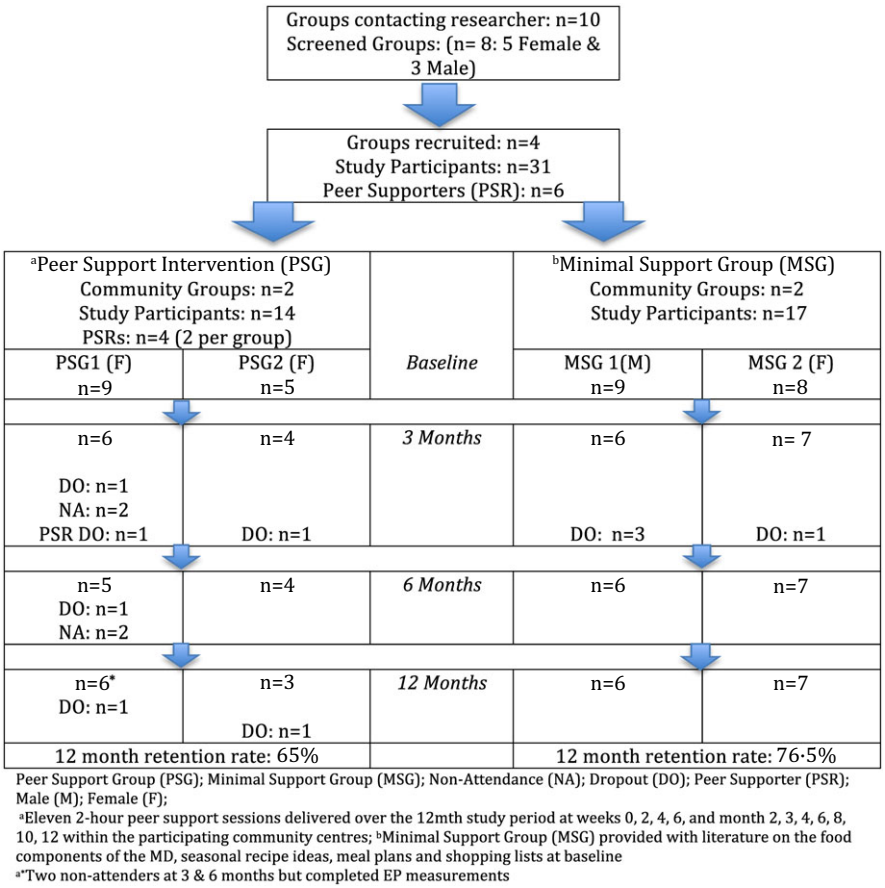

Fig. 1. Overview of the study design, recruitment and retention rates.

questionnaires at follow-up (*n* 1) and the diet upsetting symptoms of diverticulitis (*n* 1). One PSR dropped out due to 'personal reasons'; however, a 'personality clash' with several group members appeared to have contributed to this when discussed. The protocol stated that in the event of a PSR dropping out another from the reserve list should act as a replacement. Upon consultation with the remaining PSR and PSG, the remaining PSR decided to continue the sessions independently to avoid disrupting the dynamic of the group.

Participant characteristics

The baseline characteristics of recruited participants are described in Table 3. Participants in the PSG were generally younger (54·6 ± 8·7) compared with the MSG (63·5 ± 12·1); however, this was driven by the range of ages across the four recruited groups: mean age ranged from 51·8 ± 7·3 to 67·1 ± 8·8. Only one male group was recruited to the study resulting in both PSG including women only. Participants in the PSG were also likely to be single (71·4 %) compared with 23·5 % of participants in the MSG. In terms of years spent in education, the median (interquartile range) of education levels varied within each community group ranging from 11·0 (2·0) years and 12·0 (2·0) years for both PSG1 and PSG2, respectively, and 11·0 (2·0) years and 14·0 (1·0) years for MSG1 and MSG2, respectively. Two participants within PSG1 had no formal education. Anthropometry measurements (including BMI and waist circumference) tended to be higher in the PSG compared with the MSG at baseline, and relatively fewer in the PSG were taking lipid-lowering and anti-hypertensive medication (Table 3). These data also suggest that both the PSG and MSG groups were similar in MDS and smoking status at baseline.

Intervention evaluation

Descriptive statistics were used to illustrate change in the MDS and several secondary outcomes across the study time points (Table 4). MDS scores were similar across groups at baseline increasing from 3·2 (1·8) to 5·8 (2·2) (PSG) and 3·4 (1·3) to 6·7 (2·3) (MSG) at 6 months; this increased score was maintained in both groups at endpoint with the PSG having a score of 5·4 (2·5) and the MSG group having an MDS of 6·8 (2·0) at 12 months (from 6 months).

In terms of secondary outcomes, weight decreased from 79·6 (21·2) kg at baseline to 74·3 (21·0) kg and 68·5 (14·0) kg at 6 and 12 months in the PSG but remained relatively stable at 71 kg in the MSG group across the follow-up time points. BMI decreased from 31·1 (3·9) kg/m^2 at baseline to 29·0 (2·6) kg/m^2 at 12 months in the PSG and 26·1 (4·3) kg/m^2 at BL to 25·3 (3·7) kg/m^2 in the MSG group at 12 months. Waist circumference also decreased in the PSG from 103·1 ± 12·1 cm to 96·4 ± 8·4 cm at endpoint but remained

Table 4. Mean (SD) for primary and secondary outcomes (anthropometry & blood pressure only) at baseline, 6 & 12 months in the Peer Support Group (PSG) and Minimum Support Group (MSG)

	Baseline				6-months				12-months			
	PSG *n* 14		MSG *n* 17		PSG *n* 9		MSG *n* 13		PSG *n* 9		MSG *n* 13	
Variables	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Primary outcomes												
Med diet score	3·2	1·8	3·4	1·3	5·8	2·2	6·7	2·3	5·4	2·5	6·8	2·0
Change in MDS score*	–		–		2·6	2·7	3·3	2·2	0·9	1·0	0·1	2·0
Secondary outcomes†												
Weight (kg)‡	79·6	21·2	71·0	14·6	74·3	21·0	71·0	14·3	68·5	14·0	71·2	16·9
BMI (kg/m^2)‡	31·1	3·9	26·1	4·3	30·0	4·1	25·7	3·8	29·0	2·6	25·3	3·7
WC (cm)	103·1	12·1	94·8	9·8	101·0	7·3	94·3	8·4	96·4	8·4	94·2	9·6
HC (cm)‡	107·3	13·3	104·2	5·2	108·7	9·3	103·3	5·0	108·0	4·9	104·4	4·1
Systolic BP (mmHg)	126·7	12·7	128·0	20·0	124·6	14·8	127·3	20·5	121·3	15·3	133·3	21·2
Diastolic BP (mmHg)	85·0	9·8	77·2	8·7	81·6	10·3	78·5	12·9	81·3	9·8	78·5	11·8

WHR, waist:hip ratio; WC, waist circumference; HC, hip circumference.
* Change in MDS calculated at 6 months from baseline (adoption) & 12 months from 6 months (Maintenance). Change has been calculated in *n* 7 of the 9 PSG who completed both MDS measurements at 6 and 12 months (*n* 2 PSG participants did not complete an MDS score at 6 months but finished the study and completed an MDS score at 12 months and *n* 2 different PSG participants completed 6 month measurements but not 12 months).
† Based on *n* 13 (MSG) & *n* 9 (PSG) at 6 months & *n* 13 MSG and *n* 6 (PSG) at 12 months.
‡ Median (IQR) for non-parametric data.

Table 5. Number of study participants (and percentages) in the Peer Support Group (PSG) and Minimum Support Group (MSG) adhering to each individual Mediterranean Diet Score (MDS) component at baseline and study endpoint

	Baseline						12 months					
MDS component	Total *n* 31		PSG *n* 14		MSG *n* 17		Total *n* 22		PSG *n* 9		MSG *n* 13	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Main cooking fat: olive or rapeseed oil	15	48·4	5	35·7	10	58·8	19	86·4	9	100	10	76·9
Use olive oil-based spreads	3	9·7	2	14·3	1	5·9	15	68·2	5	55·6	10	76·9
≥ 4 tbsp olive/rapeseed oil and/or 3 tsp spread/d	0	0·0	0	0·0	0	0·0	7	31·8	3	33·3	4	30·8
≥ 2 portions of fruit per day	9	29·0	3	21·4	6	35·3	13	59·1	4	44·4	9	69·2
≥ 3 portions of veg per day	0	0·0	0	0·0	0	0·0	3	13·6	1	11·1	2	15·4
≥ 3 servings of legumes per week	8	25·8	5	35·7	3	17·7	14	63·6	5	55·6	9	69·2
≤ 2 servings of red meat per week	16	51·6	7	50·0	9	52·9	13	59·1	6	66·7	7	53·9
≤ 1 serving of processed meat per week	8	25·8	5	35·7	3	17·7	7	31·8	0	0·0	7	53·9
2 servings of chicken/turkey per week	5	16·1	1	7·14	4	23·5	6	27·3	3	33·3	3	23·1
≥ 3 servings of fish per week	7	22·6	3	21·4	4	23·5	11	50·0	3	33·3	8	61·5
Preferentially consume wholegrain bread and/or cereal and/or rice and/or pasta instead of non-wholegrain (white) varieties	18	58·1	7	50·0	11	64·7	18	81·8	6	66·7	12	92·3
≥ 3 servings of natural nuts per week	4	12·9	3	21·4	1	5·9	5	22·7	2	22·2	3	23·1
Sweet foods (biscuits, cakes, confectionary consumed ≤ 3 times per week	4	12·9	4	28·6	0	0·0	2	9·1	1	11·1	1	7·7
Moderate alcohol consumption (1–3 glasses or equivalent ≥ 3 d/week)	5	16·1	0	0·0	5	29·4	5	22·7	1	11·1	4	30·8

stable in the MSG group across the follow-up time points. Systolic and diastolic BP also decreased in the PSG and increased in the MSG group across time points. Within the PSG, there appears to be a trend for improvements in several risk factors associated with CVD, as supported by the changes in anthropometric measurements and blood pressure across follow-up time points. However, this should be considered with caution due to the descriptive nature of the data, the small sample size and the number of participants lost to follow-up (Table 4). Inferential statistical analysis was not advised or conducted due to the pilot nature of this intervention.

Individual components of the Mediterranean Diet Score

At baseline, the most adhered to components of the MD in the total study sample were (1) *preferential consumption of wholegrain foods* with *n* 18 of 31 (58·1 %) study participants adhering to this component, (2) *limiting consumption of red meat to ≤ 2 servings of red meat per week* (*n* 16 of 31 (51·6 %)) and (3) consumption of olive oil or rapeseed oil as their main cooking fat (*n* 15 of 31 (48·4 %)). The least adhered to components of the MDS score (at baseline) were (1) consumption of ≥ 3 portions of vegetables per day (*n* 0 of 31 (0·0 %)), (2) ≥ 4 tbsp consumption of olive or rapeseed oil or 3 tsp spread/d (*n* 0 of 31 (0·0 %)) and (3) consumption of olive oil-based spreads (*n* 3 of 31 (9·7 %)). At 12 months (study endpoint), the most adhered to components of the MDS in those completing the study were (1) consumption of olive oil or rapeseed oil as the main cooking fat (*n* 19 of 22 (86·4 %)), (2) preferential consumption of wholegrain foods (*n* 18 of 22 (81·8 %)) and (3) consumption of olive oil-based spreads (*n* 15 of 22 (68·2 %). The least adhered to components

of the MDS at study endpoint were (1) consumption of confectionary and sweet foods ≤ 3 times per week (*n* 2 of 22 (9·1 %)), (2) consumption of ≥ 3 portions of vegetables per day (*n* 3 of 22 and 13·6 %)) and (3) consumption of ≥ 3 servings of natural nuts per week (*n* 5 of 22 (22·7 %)).

Acceptability and tolerance of the Peer Support intervention

PSG participants completing follow-up attended an average of six of eleven sessions; reasons provided for missing sessions were conflicting schedules, work commitments or holidays. The five-item tolerance questionnaire was completed by 61 % (*n* 18) of participants at 12 months: *n* 6 of 14 (43 %) PSG and *n* 12 of 17 (71 %) MSG participants. Fruit and vegetables, olive oil and reducing red and processed meat were the most '*acceptable*' dietary changes, whereas several participants within the PSG stated that nuts and oily fish were '*unacceptable*' due to the taste and/or texture. These qualitative findings are supported by quantitative data presenting the individual component score for each MDS item across groups and time points (discussed above), with the exception of adherence to the ≥ 3 portions of vegetables per day, as the quantitative data suggest low adherence to this component at both baseline and endpoint. When asked: *'how is your general health now (compared to baseline)?'* all PSG and 61·5 % of MSG participants said their health was '*better*' with reasons including '*more energy*', '*less bloating*' '*reduction in swelling associated with arthritis*' and *'skin feeling better'*. In terms of side effects associated with following an MD, one participant in the PSG reported that *'wholemeal foods sometimes upset Irritable Bowel Syndrome'*.

As an objective measure of nutritional status and adherence to the intervention, we requested a saliva and urine sample from all study participants. At baseline, 84 % of participants provided a saliva sample and 97 % a urine sample compared to only 48 % and 61 % for each respective measurement at endpoint. This was generally due to an unwillingness to provide the samples, but in a few cases, participants had a blocked nose, which inhibited the use of the saliva testing kit. These samples were not analysed due to the limited number of participant samples provided at follow-up.

Process evaluation

Intervention resources and implementation. Six of the nine participants completing final follow-up measurements within the PSG also completed a structured process evaluation interview, which was used to determine the acceptability of the PSG and its components. There was a consensus amongst those interviewed that the location within the community centres was convenient. The educational materials provided – including the provision of recipe books and shopping lists as well as tasting sessions where participants shared dishes and tried new foods – were beneficial:

> *I:* 'What is your opinion about the seasonal recipe booklets/shopping lists? Did you find them useful?'
> P12: *I did actually, I done the soups and stuff . . . yeah, they were helpful'*
> P11: *'they were helpful'*
> P31: '*Yes, I look over them every so often'*
> I: what did you enjoy most about the programme?
> P12: *'the wee chats with everybody . . . also some samples that we actually tried which was nice'*

Participants within the intervention group found the social support element useful to share experiences and learn from each other, which maintained motivation to attend sessions and modify behaviour:

> I: 'What helped keep people in the group motivated to keep them on track (with the PSG intervention)?'
> P11: *'There was four of five of us doing it at a time and you know it was supporting each other' . . . .'are you not on the med diet?? – Get rid of that aul white bread!'* (in reference to a lunchtime conversation within the centre)
> P13: *'I think because we all kind of worked together as well so it's like 'are you going this week?'*

Feedback on personal planners and goal setting suggested that these were not used and generally not helpful for encouraging behaviour change:

> P11: '*I did set goals in class . . . I think mine was quite repetitive . . . introduce more of this and more of that and every time I wrote: introduce more natural nuts, but I didn't do it because they're so yuk!'*
> P13: *'not really that much – it wasn't that useful I found'*
> P35: '*Sometimes it was a pain. You couldn't really be bothered filling it in to be honest with you.'*

These views were supported by the PSR who were trained to encourage participants to set SMART goals but appeared to face resistance to this element of the PS intervention and expressed difficulties in encouraging goal setting:

> I: 'What aspects of the programme did you think they (study participants) were more responsive to?'
> P2: '*They loved the recipe books and you know the wee shopping lists . . . .the planners: it was hard to get them to take them out but I kept trying'*

End-of-study interviews with the PSR (*n* 3) provided positive reviews on the support and training received throughout the study duration and intervention delivery. A PSR suggested creating a discussion forum – or similar method of communication and engagement in future studies – to provide an opportunity for PSR to remain in contact after the initial training and to share experiences with other PSR during delivery of the intervention; although the pairs of PSRs (matched to each PSG group) were in regular contact, it was suggested that such a forum could provide an extra element of support and sharing of experiences across the wider PSR group.

Process evaluation feedback from participants in the MSG, receiving education materials only, was generally positive and the majority of participants across the group felt that the MD resources such as the shopping lists, meal plans and seasonal recipes books were useful and easy to understand.

Outcome data collection. Evaluation data suggested that some individuals found the data collection process challenging, particularly questionnaire completion; in reference to baseline data collection a dropout participant remarked: '*you're a bit like a paratrooper if you get through that bit'* with another suggesting that this *'affected the responses given'*.

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Observations from the research team completing data collection suggested that the literacy levels of participants influenced the level of understanding, ability to complete questionnaires and the amount of support needed from the researcher for completion.

Discussion

This study explored the feasibility of implementation of the TEAM-MED peer support intervention to encourage adoption and maintenance of an MD, in established community groups, in comparison to a less intensive minimal support group. Challenges were faced in terms of recruitment of community groups, and recruitment of participants within the groups, with a relaxation of inclusion criteria midway through recruitment, while retention of participants throughout the study duration and completion of outcome measurement was also difficult, leading to concerns about feasibility without study design changes. These challenges meant that drawing a conclusion regarding the use of established community groups rather than newly formed groups to test the peer support intervention is not possible.

An increase in MDS was observed in both the PSG and the MSG at 6 months and was maintained at 12 months suggesting the adoption of components of an MD pattern by both groups, and – although descriptive – trends towards improvement in CVD risk factors were observed in the PSG group only. The most adhered to components of the MDS at endpoint were preferential consumption of wholegrain foods, use of olive oil as the main cooking fat and use of an olive oil-based spread. The least adhered to components were limiting confectionary, meeting recommendations for daily vegetable intake and consumption of natural nuts. End-of-study evaluation interviews with the PSG highlighted the beneficial impact of intervention participation on general health and provided useful information on intervention tolerability, highlighting the most 'acceptable' and 'unacceptable' components of the MD intervention in this group, further supporting the quantitative findings. Future interventions should consider the challenges involved in the adoption of specific MDS components in particular populations, considering additional behaviour change techniques for specific dietary components and placing an emphasis on those deemed harder or 'less acceptable' to change including vegetables, nuts and fish.

The study recruitment target was not met, and numerous challenges were encountered regarding implementation and evaluation of the intervention in an established community group setting. These challenges and proposed modifications/strategies for future learning will provide valuable lessons for researchers developing similar group and community-based, peer support interventions in this population.

Group-based and individual-level screening adds complexity to the recruitment process therefore thorough planning and a pragmatic approach is necessary to achieve recruitment targets and ensure a representative sample

The research team used a similar recruitment strategy to that of the original TEAM-MED study[17], but this was more challenging in a group setting due to the group consensus necessary for participation and the eligibility requirement that the majority of the individuals within the group (75 %, later changed to 50 %) needed to also meet individual-level eligibility requirements.

A similar, group-based recruitment approach within a community setting in NI – to encourage physical activity in older female adults for CVD risk reduction – was more successful with 87 % of group members recruited and a 78 % retention rate[39]. Within this study, community groups were directly invited to participate and due to the nature of this intervention (education sessions to encourage physical activity), there were no exclusion criteria for individual members. Our group-based recruitment strategy may have proved more challenging due to the twofold screening and eligibility requirements. Although this approach was necessary to address the aim of this study, acknowledging the associated challenges and adapting less stringent eligibility criteria may be a consideration of future work.

In the initial stages of the study, a decision was made to modify several eligibility criteria to provide some flexibility and a less stringent approach to the recruitment process. One such modification was changing the definition of low MD adherence at baseline from an MDS cut-off of ≤ 3 to ≤ 5 (of 14). Similarly, a recently conducted intervention by our research group – the THINK-MED feasibility study which recruited a sample of NI patients with Mild Cognitive Impairment – used a score of ≤ 4 as a cut-off for baseline MD adherence and faced similar recruitment challenges[40]. Identifying an appropriate cut-off for the baseline MDS is important to ensure that individuals recruited to the study have a low enough score to obtain optimal benefit from the dietary intervention, but where it is not so restrictive that it excludes individuals who would otherwise be eligible and may benefit from participation. Many previously published interventions have recruited participants with higher baseline MDS, some as high as nine[41] – these studies are generally completed in Mediterranean populations where baseline adherence to a MedDiet would be higher than in a Northern Irish population. Given that NI is unlikely to have high MedDiet adherence across the population – and the fact that even those with moderate adherence may benefit from change – larger intervention studies may consider omitting this as an inclusion criteria, but measure it – and if necessary adjust for it within their analysis.

More female than male groups contacted the research team to request further information on the study. The reason for the lower engagement from male only groups is unknown, but this contributed to the imbalance in the baseline characteristics of participants and the recruitment of only one male group. Sex-specific group and community-based interventions have shown promise at encouraging health behaviour change in overweight men[18,19]. The recruitment strategy of future large-scale studies should consider techniques for engaging male community groups and could consider invitation rather than study advertisement as an option, with a focus on organisations and support groups engaging individuals at increased CVD risk. The inclusion of a male service user for Patient and Public Involvement (PPI) in any future intervention is another possible option to address this imbalance in sex[42].

Refinement of the data collection process and a focus on core outcomes are necessary to ensure data quality and sustained participation.

The primary outcome assessment – the MDS score – a 14-item questionnaire was used to assess baseline MD adherence and adoption of the MD in this study. Both groups demonstrated a > 2-point increase at 6 months, also maintained at 12 months, and a two-point increase in MD score have been associated with a 10 % decrease in CVD[1]. A limitation of this dietary score is its subjective nature as it could be influenced by an individual's participation in an MD intervention leading to a social desirability response bias[43]. To ensure robustness of the primary outcome in future interventions, additional measures to determine adoption of an MD should be considered in combination with the MDS score.

The amount of outcome data collected within the study were comprehensive and included multiple questionnaires and assessment tools to account for potential mediators of dietary behaviour change as well as exploring potential intervention moderators. Whilst collection of such data is important to our understanding of a complex behaviour change intervention[22], this should not be burdensome to participants or at the expense of data quality. Future interventions should consider the format of data collection (written questionnaires; use of online survey software; accessibility and literacy requirements) prioritising core outcomes to ensure data quality, limit questionnaire fatigue[44] and reduce study attrition.

Use of a suitable framework to assess, plan and deliver the intervention components will enhance intervention fidelity.

Comprehensive consideration of methods to enhance the fidelity of intervention delivery was implemented during the development of the TEAM-MED intervention[17]; however, the group-based approach to intervention delivery was challenging. This was due to difficulties in synchronising multiple individual calendars to ensure the dates and timing of the PSG intervention sessions were convenient for all group members. This was anticipated and planned for: if a participant missed a session, the PSR discussed the content of the missed session with the person – either by a phone call or in person – prior to delivery of the next session. In future, it may be useful to record video or audio of all sessions so that PSG participants unable to attend have access to the content and full discussion of the sessions, or consider offering remotely – a more realistic option post COVID than when we initially designed and completed the intervention. As suggested by a PSR, the use of a discussion forum or similar method of engagement – to allow PSR to remain in contact after training and throughout the duration of the intervention delivery – may also provide a useful resource for support for PSR and may enhance intervention delivery. The National Institute of Health's Behaviour Change Consortium's Best Practice Guidance and Recommendations for 'Enhancing Treatment Fidelity in Health Behaviour Change Studies' offers a useful guide and key considerations and may be a useful framework to enhance the fidelity of future interventions[45].

PSR were trained to encourage participants to set SMART goals during delivery of the intervention[26,27] but faced resistance to this element of the PS intervention; additional strategies to explore the barriers and facilitators of goal-setting behaviour within this population – and techniques to further promote self-efficacy and self-motivation of group participants – may also be necessary for future interventions.

Prioritisation of social support and social network data

The intervention was developed within a social support framework defined as '*the process through which social relationships might promote health and wellbeing*'[46] and recruited '*established groups*' in the hope that a social support structure would already exist which may assist the behaviour change process[24]. However, the definition of a '*regular user*' may vary between organisations and the extent of '*relationships*' between existing members may differ; it is important to acknowledge that some group members may have more established social support than others, as '*hidden*' social networks may influence engagement and participation with the programme and therefore behaviour change[47]. The social support questionnaire used within the current intervention measured the types and sources of social support, and there were no differences in social support scores between groups at baseline or any follow-up time point (data not presented); however, we did not collect data on existing friendships and social networks present within groups at baseline, but this is also an important consideration. Future larger scale trials recruiting within a CRCT design should consider the group dynamic and the extent to which groups are established socially at baseline and throughout follow-up[48]. This could be achieved with the collection of brief information on existing friendships or relationships at study time points so that any analysis to determine an intervention effect can examine how social support and social networks are influencing behaviour change within and between groups[47,49].

The loss of a PSR during the process highlighted the potential for negative social interactions – '*personality clashes*' – to occur when pairing PSRs from outside the community with established community groups. Consideration should be given to the impact of this process on group dynamics and the potential of creating an unintended power hierarchy, changing the dynamic from peer-support to a teacher–student relationship. A possible alternative option in a large-scale study is to recruit PSR directly from the same community – for example, by asking the community group to nominate a member to be trained as a PSR – or alternatively, to recruit a reserve of PSR from the community group members during the initial phase of the study – similar to the approach by Smith et al in their intervention in patients with diabetes[50]. Within the original TEAM-MED intervention[17], PSR would not have been considered '*outsiders*' in a newly formed group. PSR recruited from within the same community may lead to a more trusting and open environment if participants feel that the PSR are also '*like them*'. This would increase the likelihood of study participants valuing their PSR, which will have positive implications for engagement and participation in the intervention.

Strengths and limitations

This study explored the feasibility of delivering a peer support intervention for encouraging the adoption and maintenance of

an MD in established community groups within a NI population and of testing its effectiveness in a cluster randomised controlled trial. We gathered both quantitative and qualitative data to indicate the acceptability of the intervention and the trial design to participants. The intervention was developed using the Medical Research Council guidance for developing and evaluating complex interventions thus ensuring a robust framework for the development, implementation, delivery and evaluation of the TEAM-MED intervention in this group. Validated measurement tools were used where possible to collect information on outcome measurements. The study has several limitations/findings relevant to the feasibility of the intervention delivery and trial design, including (1) a smaller, less representative sample than intended due to challenges with recruitment and study retention, (2) the MSG is not a true control group as participants in this study arm were provided with written education materials on the MD which appears to have encouraged dietary change and may have weakened any changes observed between the PSG and the MSG and (3) due to limited time and resource constraints, we did not complete a cost-effectiveness analysis.

Conclusion

This feasibility study to evaluate an MD PS intervention for encouraging adoption and maintenance of an MD in already established community groups compared with a minimal intervention group suggests an increase in MD adherence in both groups at 6 months, maintained at 12 months, with a trend in descriptive data towards improvement in CVD risk factors observed in the PSG group. Process evaluation interviews were positive in terms of the acceptability of the MD resources and the setting of intervention delivery and highlighted that some MD foods were less tolerated than others (including fish and nuts due to their taste and texture). Challenges were encountered with recruitment and retention of both community groups and participants, suggesting that a definitive study using the current trial design is unlikely to be feasible and that the effectiveness of a peer support intervention encouraging adherence to an MD should be tested using refined methods. Lessons learned will be useful to other researchers planning future complex health and/or peer support community-based interventions.

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R. F. O'N. and L. McG. managed the study and led the details of the protocol development and conduct of the study, while S. M. W. also contributed to data entry and analysis. S. E. M. and C. T. McE. developed the TEAM-MED intervention tested in established community groups here. F. K. and M. E. C. advised on trial design and feasibility issues. R. F. O'N. initially drafted the manuscript, and all authors critically revised it. I. Y. and M. C. McK., along with J. V. W., initially conceived the study design and designed the interventions and evaluation. J. V. W. was principal investigator and led the study design and was responsible for its conduct. All authors contributed to data interpretation and critically evaluated the manuscript as well as agreeing to the current submission.

There are no conflicts of interest.

Supplementary material

For supplementary material/s referred to in this article, please visit https://doi.org/10.1017/S0007114521004050

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