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MAP: Movement through active personalised engagement

Submission date
13/03/2017

Recruitment status
No longer recruiting

Registration date
14/03/2017

Overall study status
Completed

Last Edited
13/12/2021

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In developed countries approximately 25-55% of people at the age of 60 have two or more long-term health conditions (multiple chronic conditions). Having two or more long-term conditions can negatively impact on people's lives and can lead to disability, poor quality of life and frailty. These problems are made worse with age, social deprivation and with people from Black and Minority ethnic backgrounds. A team of clinicians and researchers at the University Hospitals of Leicester have developed a group education programme (MAP programme) which aims to help people to manage their long-term health problems. The aim of this study is to evaluate the effectiveness of MAP in helping people with two or more long-term health conditions.

Who can participate?
Adults aged 40-85 who have two or more long-term health conditions and access to a mobile phone.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the MAP programme. This involves attending four sessions lasting around 1.5 hours each, spaced two weeks apart. The sessions are led by a trained facilitator and involve discussions about being active, managing emotions, treatments and communications. After the first education session participants are sent a series of automated motivating text messages. Those in the second group continue as usual for the duration of the study. At the start of the study and then after six and 12 months, participants in both groups complete questionnaires and assessments to assess how active they are, how well they are managing their conditions and quality of life.

What are the possible benefits and risks of participating?
Whilst no direct benefits can be guaranteed, it is hoped that taking part in the study will still be a positive experience for those who attended. Half of the participants will attend the MAP programme, and, in addition, both groups will receive a health check during their clinic visits. There are no notable risks involved with participating.

Where is the study run from?
Leicester Diabetes Centre (UK)

When is the study starting and how long is it expected to run for?
November 2014 to May 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Patrick Highton, ph204@leicester.ac.uk

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
33099

Study information

Scientific Title
Promoting physical activity through group self-management support for those with multimorbidity: a randomised controlled trial

Acronym
MAP

Study objectives
The aim of this study is to evaluate the effectiveness of a structured education programme designed to help people with two or more long-term health conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)

West Midlands - South Birmingham Research Ethics Committee, 16/01/2017, ref: 16/WM/0505

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Health services and delivery research; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
After recruitment participants will be randomly assigned to two groups in a 1:1 ratio, statified by gender (men; women), and ethnicity (White European; other)

Intervention group: Participants will be invited to attend a group structured education programme - the MAP programme. They will also receive regular motivational text messages during the study period. The MAP programme consists of four sessions which last approximately 1.5 hours each and are two weeks apart. The sessions focus on personalised goal setting to increase physical activity and health related self-management activities, which impact on quality of life. Short motivational text messages will be sent to participants following the first education session. The text messages will be automated, unidirectional and will incur no charge to participants. The messages are motivational and will promote health behaviour change. The MAP education sessions will commence within approximately one month of recruitment. Participants will attend four education sessions. There will be approximately two weeks interval between the sessions. Short text messages will start soon after the first education session and will last up to the 12 month clinical assessment of participants. The frequency of the text messages will vary throughout the follow up period, i.e. up to the 12 month visit.

Control group: Participants will continue receiving their routine care in line with their clinical care team recommendations, i.e. there will be no change in their routine care.

Participants in both groups will be followed up for 12 month: they will be invited for clinic assessment and data collection. This will conclude participation to the study.

Intervention Type
Other

Primary outcome(s)
Average daily physical activity is measured using an accelerometer and physical activity questionnaires (RPAQ and SEE) at baseline and 12 months

Key secondary outcome(s))
Current version as of 06/04/2018:
1. Self-efficacy for managing chronic disease and exercise is measured by Chronic Disease Self-efficacy Scales at baseline, 6 and 12 months
2. Medication adherence is measured using the ASK 12 (Adherence Starts with Knowledge)

Questionnaire at baseline and 12 months
3. Quality of life is measured using the HADS and EQ-5D-5L questionnaires at baseline and 12 months
4. Lifestyle behaviours other than physical activity will be measured by food intake and sleeping pattern questions at baseline and 12 months

Original version:
1. Self-efficacy for managing chronic disease and exercise is measured by Chronic Disease Self-efficacy Scales at baseline, 6 and 12 months
2. Medication adherence is measured by The Morisky Medication Adherence scale (MMAS-8) at baseline and 12 months
3. Quality of life is measured using the HADS and EQ-5D-5L questionnaires at baseline and 12 months
4. Lifestyle behaviours other than physical activity will be measured by food intake and sleeping pattern questions at baseline and 12 months

Completion date
10/04/2019

Eligibility

Key inclusion criteria
1. Good understanding in written and verbal English
2. Able to give informed consent
3. 40-85 years old inclusive
4. Have two or more chronic conditions
5. Have access to a mobile phone for use in potential study activities
6. Able to walk independently

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
353

Key exclusion criteria
1. Limited understanding of written and verbal English
2. Dementia, learning disability, mental health disorders other than depression or epilepsy
3. Palliative care
4. Pregnancy
5. Currently participating or participated in another interventional trial in the previous 12 weeks

6. Patients with frailty. The definition of frailty will be at the investigator's discretion and based on patients:
6.1. Living in care homes or institutions
6.2. Having support for daily activities such as washing, cooking, household tasks etc.
6.3. Having had unintentional significant weight loss in the last 3-6 months
6.4. Having BMI less than 18.5kg/m2

Date of first enrolment
14/06/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Diabetes Centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made publically available due to ethical restrictions. An anonymized minimal dataset will be made available to bonafide researchers interested in collaborative research through requests sent to the lead author.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2021	13/12/2021	Yes	No
Protocol article	protocol	20/10/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3	09/02/2017	14/03/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		10/09/2019	28/04/2020	No	No