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Game of Stones: Helping men to lose weight

Submission date
01/04/2021

Recruitment status
No longer recruiting

Registration date
14/04/2021

Overall study status
Completed

Last Edited
11/06/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Some men want to lose some weight, and this, in turn, can make them feel better and help to reduce the risk of some future health problems. However, men rarely take part in weight loss services. Together with men who have tried to lose weight, the study team has designed a new weight loss service. This text messaging and incentive research has been designed with men and for men. It aims to help men to lose weight and keep it off for at least a year

The study aims to find out if text messages (with and without cash incentives) can help men to lose weight over 1 year and keep it off for another year compared to a waiting list group, to find out the costs and benefits to the health service, and men's experiences.

Who can participate?
Adult men from varied backgrounds living in and around Glasgow, Belfast, or Bristol, with a BMI over 30 kg/m² who want to lose weight and have access to a mobile phone and can receive text messages

What does the study involve?
GP practices will send invitation letters and researchers will recruit men at community venues. Men will be allocated by chance to get text messages to help them to lose weight, or to be on the waiting list to receive the text messages. Participants will receive a step counter (pedometer) and access to a webpage with information and links about how to lose weight and maintain weight loss. Additionally, participants will receive a £20 voucher when they attend the 12 and 24 month appointments. Men will be weighed at 3, 6, 12, and 24 months, and asked questions about their health, quality of life, well-being, and experiences.

What are the possible benefits and risks of participating?
If participants take part in the trial, they will get help to lose weight, however, they may be on a 12-month waiting list for the text messages. Participants can choose how they lose weight and which information they follow. The main disadvantage of taking part is that losing weight is hard work and it can be upsetting when the desired results are not met. Participants are encouraged to come back for all appointments regardless of weight loss results, the research is interested in everybody. Participants will receive a £20 gift voucher at the 12- and 24-month appointments to thank them for their time taking part and helping with the research.

Where is the study run from?
University of Stirling (UK) Stirling in collaboration with Queen's University Belfast (UK) and the University of Bristol (UK)

When is the study starting and how long is it expected to run for?
From October 2020 to November 2024

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

Who is the main contact?
Dr Lisa Macaulay, gameofstones@stir.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
290955

Protocol serial number
CPMS 48967, IRAS 290955

Study information

Scientific Title
Effectiveness and cost-effectiveness of text message and endowment incentives for weight management in men with obesity: The Game of Stones randomised controlled trial

Study objectives
Are automated 'Short Message System' (SMS) texts, delivered to support behaviour change, with or without endowment incentives, effective and cost-effective for weight-loss at 12 months compared to a waiting list control in men with obesity?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/12/2020, North of Scotland Research Ethics Committee 2 (North of Scotland Research Ethics Service, Summerfield House, 2 Eday Road, Aberdeen AB15 6RE; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 20/NS/0141

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
Researchers will recruit men who want to lose weight from varied backgrounds. GP practices will send invitation letters and researchers will recruit men at community venues. After receiving written consent at the enrolment appointment, participants will be randomised using a secure

remote web-based system provided by the CHaRT CTU. The CHaRT randomisation service is independent of the data management and statistical team at CHaRT who will be undertaking the outcome data analysis. Randomisation will be stratified by trial centre. Men will be randomly allocated (1:1) to receive text messages to help them to lose weight for 12 months, or to be on the 12-month waiting list to receive the text messages. Men will be weighed at 3, 6, 12, and 24 months and asked questions about their health, quality of life, well-being, and experiences at 12 months.

Intervention Type
Behavioural

Primary outcome(s)
Weight loss is measured as % of baseline at 12 months measured using calibrated medical scales at baseline and 12 months

Key secondary outcome(s))
Current secondary outcome measures as of 18/05/2023:

1. Weight loss is measured in kg using calibrated medical scales at baseline, 3, 6, 12, and 24 months
2. Mental well being is measured by the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and 12 months, and the EuroQol 5-dimension (EQ-5D) quality of life questionnaire (Anxiety and Depression Dimension) and PHQ-4 at baseline, 12, and 24 months
3. Health economic outcomes are measured by the EQ-5D quality of life questionnaire and NHS Health care use questionnaires at baseline, 12, and 24 months
4. Health behaviours (physical activity, smoking status, and alcohol intake) measured using a self-report questionnaire at baseline and 12 months
5. Weight management strategies used measured by self-report questionnaire at baseline, 12, and 24 months
6. Confidence in ability to lose and maintain weight loss is measured by self-report questionnaire at baseline and 12 months
7. Weight stigma is measured by WSSQ at baseline and 12 months
8. Participant satisfaction is measured by self-report questionnaire at 12 months
9. Experience and behaviours is examined through qualitative data taken in interviews at 12 and 24 months

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Previous secondary outcome measures as of 14/12/2021:

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2. Mental well being is measured by the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) and PHQ4 at baseline and 12 months
3. Health economic outcomes are measured by the EuroQol 5-dimension (EQ-5D) quality of life questionnaire and NHS Health care use questionnaires at baseline, 12, and 24 months
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7. Participant satisfaction is measured by self-report questionnaire at 12 and 24 months
8. Experience and behaviours is examined through qualitative data taken in interviews at 12 and 24 months

Completion date
30/11/2024

Eligibility

Key inclusion criteria
1. Men aged ≥18 years
2. BMI ≥30 kg/m²
3. Understand study information and able to give informed consent
4. Resident in and around Glasgow, Belfast, or Bristol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Total final enrolment
585

Key exclusion criteria
1. Inability to understand the trial or the English language SMS intervention
2. No mobile phone access
3. Planning to move out of the area within 12 months
4. Current or recent (within last 6 months) participation in a research weight loss intervention study (participants from the feasibility study are welcome to participate in this RCT)
5. Plan to have bariatric surgery within 12 months
6. For GP screening prior to sending invitation letters:
6.1. Known terminal illness or severe psychiatric illness
6.2. Known impaired cognitive or visual function that would limit understanding of study information and SMS
7. Whilst there is no upper age limit exclusion to this trial, researchers taking consent will be trained to consider whether participation is appropriate for individual participants (for example the levels of frailty allowing standard weighing procedures to be followed or sufficient cognition to understand consent and participation procedures)

Date of first enrolment
13/07/2021

Date of final enrolment
24/05/2022

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
University of Stirling
NMAHP Research Unit
Pathfoot Building
Stirling
United Kingdom
FK9 4LA

Study participating centre

University of Bristol
Bristol Medical School
39 Whatley Road
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BS8 2PS

Study participating centre
Queen's University Belfast
School of Medicine
University Road
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United Kingdom
BT7 1NN

Sponsor information

Organisation
University of Stirling

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent. Any hard copy data will be stored at Stirling University and requests to access data are administered through the University's data archive DataSTORRE. The investigator site files will be archived at each centre. Following publication of the results, an anonymised participant level dataset and statistical code for generating the results will be available.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2024	15/05/2024	Yes	No
Protocol article		22/07/2022	25/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Cost-effectiveness analysis	21/05/2025	11/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 2.0	21/06/2023	21/11/2023	No	No
Statistical Analysis Plan	version 1.2	25/06/2024	28/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes