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Using "IF-THEN" plans to increase physical activity

Submission date 04/06/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 17/06/2019	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 06/09/2022	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Implementation intentions (i.e., making if-then plans) are effective at changing behaviour. However, despite many studies showing this effect there are few studies that have been conducted on large samples and for more than a short term follow up. The aim of this study is to test the effectiveness of using two different interventions (standard volitional help sheet and single situation volitional help sheet) at increasing physical activity in comparison to a control group.

Who can participate?
UK adults who are capable of engaging in physical activity

What does the study involve?
Participants complete a series of questionnaires about their physical activity and are then randomly allocated to one of the three groups. The standard volitional help sheet includes a list of situations when people might not want to be physically active (e.g., If I'm tempted not to be physically active when I'm under a lot of stress) and a list of solutions to overcoming these (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward). Participants are asked to draw a line from the situations that are relevant to them to their chosen solutions. They can create as many situation and solution pairs as they want. The single situation volitional help sheet includes a stem but not a specific situation (e.g., If I'm tempted not to be physically active…) and a list of solutions to overcoming this (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward). Participants are asked to draw a line from the stem to them to their chosen solutions. They can create as many pairs as they want. The control group includes the same list as the standard volitional help sheet but people are asked just to tick situation and solutions that are relevant to them. After 6 months participants are asked the same physical activity questions to see if the intervention has increased their physical activity and also find who it will work best for.

What are the possible benefits and risks of participating?
The benefits of participating are that participants may increase their physical activity. There are no risks of participating.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
May 2019 to June 2020

Who is funding the study?
Tesco (UK)

Who is the main contact?
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Additional identifiers

Protocol serial number
2019-7332-10682

Study information

Scientific Title
Using "IF-THEN" plans to increase physical activity

Study objectives
Current study hypothesis as of 18/10/2019:
1. The two conditions that complete a volitional help sheet (standard VHS and single situation VHS) will report greater physical activity and lower sedentariness at follow up than the control condition
2. Increases in physical activity/reductions in sedentariness will be associated with improved subjective well-being
3. The VHS interventions will be most effective for those who have developed high habits, awareness of standards, self-monitoring, self-regulatory effort, capabilities, opportunities and motivations to increase physical activity and are currently not meeting health behaviour guidelines (including physical activity, smoking, alcohol consumption and diet)

Previous study hypothesis:
1. The two conditions that complete a volitional help sheet (standard VHS and single situation VHS) will report greater physical activity and lower sedentariness at follow up than the control condition
2. Increases in physical activity/reductions in sedentariness will be associated with improved subjective well-being
3. The VHS interventions will be most effective for those who have high habits, awareness of standards, self-monitoring, self-regulatory effort, capabilities, opportunities and motivations to increase physical activity and are currently not meeting health behaviour guidelines (including physical activity, smoking, alcohol consumption and diet)

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 21/06/2019, University Research Ethics Committee at the University of Manchester (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL; 0161 275 2206/2674; research.ethics@manchester.ac.uk), ref: 2019-7332-10682

Primary study design
Interventional

Study design
Three-arm randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Physical activity

Interventions
Participants complete a series of questionnaires about their physical activity and are then randomly assigned to one of the three conditions:

1. The standard volitional help sheet includes a list of situations when people might not want to be physically active (e.g., If I'm tempted not to be physically active when I'm under a lot of stress) and a list of solutions to overcoming these (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward). People are asked to draw a line from the situations that are relevant to them to their chosen solutions. They can create as many situation and solution pairs as they want.
2. The single situation volitional help sheet includes a stem but not a specific situation (e.g., IIf I' m tempted not to be physically active…) and a list of solutions to overcoming this (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward). People are asked to draw a line from the stem to them to their chosen solutions. They can create as many pairs as they want.
3. The control condition includes the same list as the standard volitional help sheet but people are asked just to tick situation and solutions that are relevant to them.

After 6 months participants are asked the same physical activity questions to see if the intervention has increased their physical activity and also find who it will work best for.

Intervention Type
Behavioural

Primary outcome(s)
1. Physical activity is measured using the Sport England: Short active lives questionnaire and the IPAQ at baseline and 6 months follow up
2. Sedentary behaviour is measured using a sedentary behaviour questionnaire at baseline and 6 months follow up

Key secondary outcome(s)

1. Capability, opportunity and motivation (based on COM-B model) is measured using the COM questionnaire at baseline and 6 months follow up
2. Habit is measured using the self-reported habit index (automaticity scale) at baseline and 6 months follow up
3. State self-regulation is measured at baseline and 6 months follow up (Sniehotta, F. F., Scholz, U., & Schwarzer, R. (2005). Bridging the intention-behavior gap: Planning, self-efficacy, and action control in the adoption and maintenance of physical activity. Psychology & Health, 20, 143–160. http://dx.doi.org/10.1080/08870440512331317670)
4. Daily smoking, weekly alcohol consumption and daily fruit and vegetable intake measured using three questions at baseline and 6 months follow up
5. Subjective well-being measured using the Office of National statistics measure of wellbeing at baseline and 6 months follow up

Completion date
28/02/2020

Eligibility

Key inclusion criteria
UK adults who are capable of engaging in physical activity

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
3085

Key exclusion criteria
1. Children
2. People who are not capable of engaging in physical activity
3. People not based in the UK

Date of first enrolment
08/07/2019

Date of final enrolment
16/08/2019

Locations

Countries of recruitment

United Kingdom

Study participating centre
YouGov will be distributing the questionnaires via its online platform
United Kingdom
-

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Industry

Funder Name
Tesco

Results and Publications

Individual participant data (IPD) sharing plan
The data will be shared via OSF. However, people can contact Dr Tracy Epton (epton.tracy@gmail.com). The data will be available for 10 years, data will be freely available for anyone who wishes to use it. Consent from participants was obtained. The data will be fully anonymised.

The statistical analysis plan has been uploaded as an additional file (added 31/10/2019)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		29/10/2019	31/10/2019	No	No