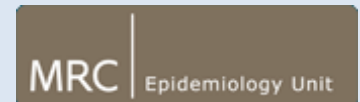




Very Brief Interventions Study: Potential efficacy, fidelity, feasibility and acceptability of techniques to promote physical activity in primary care

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VBI Programme Team



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Overview

- ❖ **VBI programme (Very Brief Interventions to promote physical activity):**
rationale, aims and workstreams
- ❖ **Process Evaluation: The case of VBI**
- ❖ **VBI Feasibility Study and Pilot Trial:**
testing promising VBIs prior to a substantive trial





VBI Programme: rationale

- ❖ Important to reduce the public health burden due to inactive lifestyles.
- ❖ Only 6% of men and 4% of women meet current PA recommendations for 30mins per day. [Health Survey for England 2008]
- ❖ Need for scalable interventions which can reach a large proportion of the adult population (in addition to more intensive interventions targeting those at higher risk).
- ❖ NHS Health Checks aim to lower risk of developing heart disease, stroke, diabetes and kidney disease (early detection / prevention).
- ❖ Health Checks offer an ideal opportunity to deliver brief physical activity advice of approximately five minutes to a large proportion of the population.
- ❖ Very brief physical activity advice should be relatively easy and inexpensive to implement on a large scale, and a small effect could translate into a significant public health benefit.



VBI Programme: Aims

- ❖ To develop and evaluate very brief interventions (**VBIs**) to increase physical activity that could be delivered by a practice nurse or health care assistant (**HCA**) in an NHS Health Check (**HC**) or other primary care consultation
- ❖ Patients aged 40-74, not currently diagnosed with vascular disease or with certain high risk factors (e.g. high blood pressure or cholesterol) already treated by medication



Development work

Evidence synthesis

Estimate cost and effectiveness of promising VBIs from studies/reviews

Qualitative study

Integration of VBIs in NHS health checks

Expert Consultation

Health Economics

Resource use of promising VBIs
Economic model of cost-effectiveness of VBIs

Pilot Work

Feasibility Study & Pilot Trial

Develop and pilot materials
Test feasibility, acceptability, fidelity and potential efficacy
Select best-best VBI

Substantive Trial

Main trial

Estimate cost and effectiveness of best-bet VBI

VBI Programme: Workstreams

VBI VERY BRIEF INTERVENTIONS



Process Evaluation: the case of VBI

- *“Process evaluation may be used to assess fidelity and quality of implementations, clarify causal mechanisms and identify contextual factors associated with variation in outcomes”* [MRC guidance for complex interventions]*
- **This talk:** process evaluation in parallel with a pilot trial.
- **Pilot Trial:** evaluates several promising very brief interventions to promote physical activity in primary care against a control condition.
- **Process Evaluation:** used to inform the decision about the best-bet intervention to be evaluated in a substantive trial.
- **Criteria for this selecting the best-bet VBI:** include feasibility, acceptability, and fidelity (in addition to efficacy).

*Moore et al. (2013) Process evaluation in complex public health intervention studies: the need for guidance. *JECH (Online First)*



Pilot work: two phases

1 Feasibility study

2 Pilot trial



Feasibility Study (Phase 1)

Objectives:

- (i) To develop and optimise promising VBI's (identified from Evidence Synthesis, Qualitative Study and Expert Consultation)
- (ii) To develop and test pilot intervention protocols, training manual, intervention materials and quality assurance (fidelity) instruments

Process Evaluation:

- Fidelity
- Feasibility
- Acceptability of the VBIs



Pilot Trial (Phase 2)

Objectives:

- (i) To test the fidelity, feasibility, acceptability AND potential efficacy of the VBIs.
- (ii) To decide which single or combined VBI to take forward to evaluation in a substantive trial.

Process Evaluation:

- Intervention Fidelity
- Intervention Feasibility
- Intervention Acceptability
- Intervention Uptake

Outcome Evaluation:

- Efficacy



Walk

Dance

Swim

Run

Stretch

Cycle

Move!

Feasibility Study (Phase 1): Fidelity, Feasibility & Acceptability of the VBI's

Generation of VBI Short-list for Phase 1

Sources of Evidence

Evidence Synthesis
Scoping Review of BCTs (behaviour change techniques)
Team Discussions
Expert Consultations (practitioners, academics, end-users)
Qualitative study



Four VBIs

ALL Interventions Included:

- Physical Activity Assessment; PA recommendations; Face-to-face discussion; Written materials

VBI 1: Motivational

- Benefits of PA
- Ways of increasing PA
- Signposting to local resources, etc.

VBI 2: Action Planning

- Ways of increasing PA
- Planning Activity (What, When, Where, & With Whom)

VBI 3: Pedometer

- 10,000 steps goal
- Verbal instruction to record steps

VBI 4: PA Diary

- Ways of increasing PA
- Record daily activity
- Compare activity and goals
- Review/set new goals each week

Feasibility Study (Phase 1)

Participants

- N=68
- Recruited from 2 practices (3 Healthcare Assistants & 1 Nurse)
- Received a Health Check plus one of the 4 VBIs

VBI 1: Motivational

N= 16

VBI 2: Action Planning

N= 17

VBI 3: Pedometer

N=18

VBI 4: PA Diary

N=17

Process Evaluation

- Health Check (plus VBI) Recordings [fidelity and feasibility]
- Participant Interviews [feasibility and acceptability]
- Practitioner Interviews and on-going feedback [feasibility and acceptability]

Feasibility Study (Phase 1): Main Findings

Fidelity

- Fidelity was quite high and did not differ across the four VBIs.
- Nurses / Health Care Assistants often went into 'telling mode' rather than asking questions.

Feasibility

- All VBIs fitted comfortably into 5 minutes at the end of the Health Check.
- Nurses/HCAs reported that all VBIs were relatively easy to deliver.
- NO patient wrote an Action Plan or Set a Goal (Activity Diary) during the intervention.

Acceptability

- Nurses/HCAs reported that all VBIs seemed to be acceptable to patients.
- Patients reported that the HC was a good time to discuss PA and that having a discussion about PA was very useful.
- Patients reported that they appreciated being asked (rather than told) how they could improve their PA.
- The majority of patients said they would use the materials given and they intended to increase their PA.

Feasibility Study (Phase 1): Main Findings

Other Findings....

- Nurses / HCAs reported that they felt telling people the PA recommendations was a good idea (and something they weren't already doing as part of the Health Check).
- The majority of patients reported that they were not aware of the PA recommendations (they just knew they should 'do more').
- A number of patients reported that completing the Physical Activity Assessment helped make them aware of how little PA they were doing / where they could make improvements.

Suggestions for Improvement

- The vast majority of patients reported that there was nothing more that could have been said or done to help / encourage them to increase their physical activity. However:
- Some patients commented that they would have liked more tips for how to increase their PA.
- And many patients commented that they would have liked a Follow-up consultation (to have someone 'checking up' on their activity).

Selecting VBIs for Evaluation in a Pilot Trial (Phase 2)

Sources of Evidence

From the Feasibility Study (Phase 1):

- Health Check Recordings [fidelity and feasibility]
- Participant Interviews [feasibility and acceptability]
- Practitioner Interviews [feasibility and acceptability]

Three VBIs

~~ALL Interventions Include:~~

- Physical Activity Assessment; PA recommendations; Face-to-face discussion; Written materials

VBI 1: Motivational

- Benefits of PA
- Ways of Increasing PA
- Signposting, etc.
- Action Planning
- Activity Diary

VBI 2: pedometer

- 10,000 steps goal
- Step Chart & Pedometer

VBI 3: Motivational & Pedometer

- Benefits of PA
- Ways of Increasing PA
- Signposting, etc.
- Action Planning
- Activity Diary
- 10,000 steps goal
- Step Chart & Pedometer



Walk

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Move!

Pilot Trial (Phase 2):

Fidelity, Feasibility, Acceptability AND
Efficacy

Pilot Trial (Phase 2)

Participants

- N=384, recruited from 8 practices (So far: 298 recruited; follow-up data from 168)
- 18 practitioners trained [9 Nurses and 9 Health Care Assistants]
- Randomised to Control (Health Check only) or one of 3 Intervention conditions (Health Check plus VBI) using an *adapted cluster randomised design*.

Control

VBI 1: Motivational

VBI 2: Pedometer

VBI 3: Motivational
& Pedometer

Outcome and Process Evaluation (4 weeks post Health Check)

Outcome and Process Evaluation

Outcome Evaluation

- Objective physical activity (ActiGraph GT3X+) [efficacy]
- Self-reported physical activity (RPAQ) [efficacy]

Process Evaluation

- Questionnaire: recall, use of VBI materials, use of behaviour change techniques, feasibility, acceptability, and beliefs about being more physically active [fidelity, feasibility and intervention uptake]

In a sub-sample:

- Health Check (plus VBI) recordings [fidelity and feasibility]: n=64 (2 per condition per practice)
- Participant Interviews [feasibility and acceptability]: n=48 (2 per VBI per practice)
- Practitioner Interviews and on-going feedback [feasibility and acceptability]: n=16 (1 per practitioner)

Pilot Trial (Phase 2): Process Evaluation Measures

1. Intervention Fidelity

i.e. was the intervention delivered faithfully

2. Intervention Feasibility

e.g. could the intervention be delivered within 5 minutes; was the training provided to practitioners sufficient etc.

3. Intervention Acceptability

i.e. was the intervention acceptable to both practitioners and patients

4. Intervention Uptake

e.g. did participants recall receiving the intervention; did they use the intervention materials; what aspects of the intervention did they find the most useful; etc.

Health Check & VBI
Recordings

Patient
Interviews

Practitioner Interviews &
Ongoing Feedback

Follow-Up
Questionnaire



Process Evaluation: Example Questions

Patient Interviews

“Do you think the discussion of physical activity was tailored to you as an individual?”

“Do you think you will increase your physical activity after the discussion in today’s Health Check?”

Practitioner Interviews & Ongoing Feedback

“How did you feel the physical activity intervention flowed following on from the Health Check (i.e., the transition from the routine Health Check to delivering the PA intervention?)”

“How did patients respond to the physical activity intervention?”

Follow-Up Questionnaire

“What are the key things you remember about the discussion of physical activity?”

“Please rate how useful you found each Step in the Step-by-Step Guide by ticking the appropriate number, and writing any comments you have about each step.” [not at all useful, somewhat useful, very useful]



Phase 2 (Very) Preliminary Findings

Questionnaire Data (n=80):

- Participants who received a VBI were more likely to remember that PA was discussed in the Health Check.
- About a third of participants in all groups reported that they would like a follow-up appointment.

Patient Interviews (n=40):

- Health Check is a good time to discuss PA.
- Many reported that they already understood the importance of PA.
- No distinction between interventions.



The additional 'challenges'!

Phase 1

- ❖ Poor initial recruitment of GP practices
- ❖ Low number of health checks per week
- ❖ Logistical issues: participant recruitment
- ❖ Communication challenges
- ❖ Health check – control condition



Phase 2

- ❖ Randomisation
- ❖ Participant recruitment concerns: Participant Invitation Sheet (PIS) wording/invite procedures?
- ❖ Data collection: objective PA measures



Process Evaluation: Benefits and Challenges

❖ Benefits:

- Information about intervention **content** and **delivery**
- Highlights challenges associated with **recruitment, retention** and **wider system factors** that are important for the main trial.

❖ Challenges:

- Interpreting multiple sources of data to decide best-bet intervention
- Logistical challenges (i.e., wide geographical area)



What Have We Learned So Far?

Key conclusions:

- VBIs are acceptable and feasible within a health check.
- Process evaluation invaluable to the development of feasible and acceptable VBIs
- Process evaluation crucial for piloting procedures to be utilised in the main trial

Next steps:

- Data analysis (quantitative & qualitative)
- **Deciding which VBI to take forward to the main trial.**



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