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Physical activity monitors in the Welsh National Exercise Referral Scheme to enhance maintenance

Submission date
05/10/2015

Recruitment status
No longer recruiting

Registration date
05/11/2015

Overall study status
Completed

Last Edited
30/11/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Low levels of physical activity are associated with an increased risk of heart disease, type 2 diabetes and some forms of cancer, as well as poorer psychological wellbeing. Most adults in Wales do not currently achieve the recommended levels of physical activity. Strategies to increase people's physical activity levels, such as exercise referral schemes, have had mixed successes to date, and have often only had short-term effects. In Wales, a trial of the National Exercise Referral Scheme (NERS) demonstrated small but significant impacts on physical activity at 12-month follow-up, although the effects were limited to patients with coronary heart disease risk factors. This study seeks to assess the feasibility of adding a new motivational component to an existing effective intervention in order to enhance the effects of NERS, and support longer-term maintenance of physical activity. The new component involves a combination of a physical activity monitor (MyWellnessKey) and a support website (MyWellnessCloud). Research suggests that activity monitors may enhance physical activity levels and long-term maintenance by allowing the user to set goals and monitor how well they are doing. This study will enhance our understandings of how to integrate such technologies into existing exercise programmes, and will provide an assessment of feasibility and acceptability to inform whether and how to proceed to a larger study.

Who can participate?
People referred into the National Exercise Referral Scheme. For referral into the scheme, patients must be aged 16 or over, be sedentary (defined as not moderately active for 3 times per week), and have at least one of the following: raised blood pressure 140/90, BMI >28, cholesterol >5.0, controlled diabetes or impaired glucose intolerance, family history of heart disease or diabetes, at risk of osteoporosis or musculoskeletal pain, mild arthritis or poor mobility, mild-moderate COPD, mild anxiety or depression, or multiple sclerosis.

What does the study involve?
Participants are randomly allocated to either participate in the NERS programme, or to receive the activity monitor in addition to participating in the NERS programme. We analyse the data that is normally collected as part of NERS including participants' self-reported physical activity

levels, fitness, height, weight, waist circumference, blood pressure, general health and well-being. We also collect data about participants' levels of motivation for physical activity. Data is collected at the start of the study and at three follow-up points: when participants exit NERS after 16 weeks; at 12 months after the start of the study; and then at 16 months where we will measure physical activity. We explore whether using the activity monitors leads to an increase in levels of motivation for physical activity by comparing motivation at the start of the study, 16 weeks and 12-month follow-up in both groups. We also interview participants to explore their experiences of using the activity monitors.

What are the possible benefits and risks of participating?
Participants may benefit from the use of the activity monitors alongside their participation in the National Exercise Referral Scheme. Benefits may include increased physical activity and associated health improvements (e.g. weight loss, lowered blood pressure, improved mood). The greatest benefits are likely to be in those who adhere to both the exercise scheme and the use of the activity monitors. There are no known risks to participants of using an activity monitor - this is the only part of the intervention which is not already delivered as part of routine practice in the National Exercise Referral Scheme. Our study data collections will include a range of questionnaire measures, and there is minimal risk of these causing distress to participants. Participants will be assured of confidentiality and that they can miss any questions they do not wish to answer.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
October 2015 to September 2017

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Dr Jemma Hawkins

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The use of accelorometry-based activity monitors and linked web portal to enhance long-term maintenance of physical activity in adults: a pilot trial in an exercise referral setting

Study objectives
Low levels of physical activity are associated with an increased risk of chronic disease outcomes including heart disease, type 2 diabetes and some forms of cancer as well as poorer psychological wellbeing. The majority of adults in Wales do not currently achieve public health recommendations for physical activity. Due to the health, social and economic costs of these levels of inactivity, increasing physical activity at the population level and among at-risk populations is a public health priority. Interventions to increase individuals' physical activity levels, such as exercise referral schemes, have had mixed successes to date, and have often only demonstrated effects in the short term.

The overarching aim of the study is to evaluate the feasibility and acceptability of the intervention and its proposed evaluation methodology, in order to optimise design and delivery prior to seeking funding for an effectiveness trial. This will be achieved through:
1. Examining the feasibility and acceptability of implementing My Wellness Key activity monitors within the Welsh National Exercise Referral Scheme [NERS]
2. Investigating key methodological uncertainties in comparing the effectiveness of the enhanced intervention with 'usual practice'.

As this study is evaluating feasibility and acceptability there are no hypotheses available. However, it is anticipated that the activity monitor devices (the intervention) will enhance NERS through two key psychosocial mechanisms:
1. Goal setting and personalised feedback elements of the devices will support a sense of exercise mastery and perceived competence
2. The web platform will provide a sense of relatedness to others.

It is anticipated that these mechanisms will improve autonomous motivation for exercise, leading to greater maintenance of increases in physical activity. This study does not aim to test these hypotheses by assessing the significance of intervention effects on the primary outcome (physical activity) or likely mediators but will estimate key trial parameters (e.g. standard deviation) to inform a future trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 02, 01/12/2015, ref:189587

Study design
Single-centre pilot trial (allocation at individual-level) with embedded mixed-method process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Low levels of physical activity

Interventions
The study will compare 'usual practice' (NERS) with an enhanced exercise referral group (NERS+MyWellnessKey).

Control treatment (NERS)
The control group will receive standard practice; a 16-week structured exercise programme. Scheme participants receive a consultation with an exercise professional which includes collection of routine monitoring data, introduction to the facilities, brief motivational interviewing and goal setting. They then receive access to one to one exercise instruction and/or group exercise classes at a discounted rate. At 4 weeks patients meet with the exercise professional to review goals. At 16 weeks a consultation is held to review goals again and collect end of scheme monitoring data. The participant is then signposted to community exercise opportunities. At 8 months, the exercise professional makes telephone contact to check progress and at 12 months a final review appointment is scheduled to repeat monitoring data.

Planned intervention (NERS+MyWellnessKey)
The enhanced intervention involves an accelerometry-based activity monitor [MyWellnessKey; MWK] to be used for self-monitoring of physical activity levels in combination with a linked web platform [MyWellnessCloud] and smartphone application. The MWK has been validated in terms of device accuracy at monitoring PA level and intensity and utility at fostering increased PA levels (high concurrent validity with ActiGraph accelerometer to detect PA in lab & free living).

Components include:
1. Real-time visual feedback via a screen on the device
2. Detailed feedback on activity levels via the Cloud to indicate progress towards goals, time

spent in different activity intensities and calories burned
3. Automatised goal setting via an algorithm which sets goals in a stepwise fashion such that forward progression is mastery-based
4. Facilitation of social support for exercise via the Cloud (through involvement in group challenges and remote communication with the exercise professional) and smartphone app (being able to share details about activity completed via social media)
5. Free access to the Cloud following discontinuation of use of the MWK. Activity can continue to be monitored via manual input into the Cloud or by connecting it to another monitoring device (e.g. a smartphone application)

It is anticipated that the intervention will enhance NERS through two key psychosocial mechanisms:
1. Goal setting and personalised feedback elements of the devices will support a sense of exercise mastery and perceived competence
2. The web platform will provide a sense of relatedness to others. It is anticipated that these mechanisms will improve autonomous motivation for exercise, leading to greater maintenance of increases in physical activity.

For participants in the intervention group, NERS professionals will introduce the MWK during the 4-week appointment. A demonstration and instructions on using the device will be given. Participants will have MyWellnessCloud accounts set up during the appointment and the professional will configure initial activity goals on the MWK. Participants will be advised to use the device daily for 48 weeks (i.e. for the remaining 12 weeks in NERS and then for 36 weeks after their exit from NERS) and to return the MWK at their 12-month follow-up appointment. The device is to be worn to monitor all activity, apart from swimming/bathing. Participants will be advised to connect the MWK to a computer at least twice per week to upload data to the Cloud, receive feedback and charge the device. Participants will be asked to manually enter information about activity that the device does not readily measure, i.e. swimming, weight training, cycling. At specified time points, exercise professionals will set up group challenges via the Cloud to encourage participant engagement. At the 8-month phone call opportunities will be taken to provide reminders and encouragement to use the device, Cloud and associated features.

Intervention Type
Device

Primary outcome measure
In this pilot trial, primary outcomes are focused on feasibility and acceptability of the intervention and trial methods. We will also pilot planned primary and secondary outcomes in order to assess responsivity and sensitivity to change for a full trial. We will collect data on the potential range of effect sizes associated with the intervention. This data will be used to calculate a sample size for a subsequent full effectiveness trial, if warranted. The primary outcome in the pilot trial used to inform the sample size calculation will be physical activity at 16 months.

Secondary outcome measures
We will evaluate the effect of the intervention on the main hypothesised change mechanism (autonomous motivation) at 12-month follow-up. We will also pilot secondary outcome measures to estimate key trial parameters (e.g. standard deviation) to inform a future full trial, these are: fitness level, resting heart rate, blood pressure, waist circumference, body mass index, health-related quality of life and a cost-utility analysis.

The following measures will be collected at baseline, 16 weeks and 12 months:
1. Body Mass Index (calculated from height and weight)
2. Waist circumference
3. Blood pressure and resting heart rate
4. Fitness level (measured using Chester fitness test)
5. Health-related quality of life (measured using EQ-5D-5L47)
6. Autonomous motivation (measured using Behavioural Regulations in Exercise Questionnaire)

Overall study start date
01/10/2015

Completion date
30/09/2017

Eligibility

Key inclusion criteria
Individuals referred into the National Exercise Referral Scheme generic pathway identified as having capacity to use the activity monitors (i.e. computer access and an email address).

For referral into the scheme, patients must:
1. Be aged 16 years or above
2. Be sedentary (defined as not moderately active for 3 times per week or deconditioned through age or inactivity)
3. Have at least one of the following:
3.1. Raised blood pressure 140/90
3.2. BMI >28
3.3. Cholesterol >5.0
3.4. Controlled diabetes or impaired glucose intolerance
3.5. Family history of heart disease or diabetes
3.6. At risk of osteoporosis or musculoskeletal pain
3.7. Mild arthritis or poor mobility
3.8. Mild-moderate COPD
3.9. Mild anxiety or depression
3.10. Multiple sclerosis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
286

Total final enrolment
156

Key exclusion criteria
Individuals not referred to the NERS generic pathway and/or without computer access and an email address.

Exclusion criteria for referrals include:
1. Cardio-myopathy
2. Suspected or known aneurysm
3. Unstable or acute heart failure
4. Established coronary heart disease
5. Various uncontrolled conditions (hypertension 180/100, resting tachycardia 100bpm, diabetes, angina, epilepsy, arrhythmias, and psychiatric illness)

Date of first enrolment
04/01/2016

Date of final enrolment
04/03/2016

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
1-3 Museum Place
Cardiff
United Kingdom
CF10 3BD

Sponsor information

Organisation
Cardiff University

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30-36 Newport Road
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Sponsor type

University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Research organisation

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
As a pilot trial, dissemination plans will focus on whether and how to proceed to a full-scale trial. If progression criteria are met, findings will be discussed with the advisory group to facilitate an NIHR funding application for an effectiveness trial. If the intervention does not show sufficient promise to justify progression to a full trial, data will serve stand-alone functions in understanding processes of delivering motivational enhancement tools within ERS, and insights into how these might be refined. Abstracts describing findings will be submitted for presentation at a number of UK and international public health conferences and submitted to high impact peer-reviewed journals for publication. We will engage with policy and practice audiences through presentations of findings to NERS staff and other key stakeholders. This will involve a dissemination event as well as a report to the NERS steering group and Public Health Wales' Health and Wellbeing Best Practice and Innovation Board. We will engage DECIPHer's knowledge exchange resources, the Public Health Wales press office and Cardiff University's public relations offices to publicise a press release and blog post summarising the main findings to increase public awareness of the project and its outcomes. We will place a summary of the results of the project on the study pages of the South East Wales Trials Unit website which is accessible to the general public.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/12/2017		Yes	No
Results article	results	29/03/2019		Yes	No