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Understanding the impact upon physical activity of the Devon Active Villages intervention

Submission date
10/04/2012

Recruitment status
No longer recruiting

Registration date
10/05/2012

Overall study status
Completed

Last Edited
10/09/2014

Condition category
Other

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

Plain English summary of protocol

Background and study aims
People in developed countries are not doing enough physical activity or sport, putting them at risk of obesity, diabetes, heart disease and other health problems. The health benefits of a physically active lifestyle are well established, therefore interventions need to be developed to increase participation in physical activity. Several studies have found that delivering activity interventions (programs) to whole communities (rather than individuals) may be the key to increasing population physical activity levels. Very few studies have studied physical activity in rural communities, despite people in rural areas reporting unique barriers to being physically active. The activity programme Devon Active Villages will provide sports and activities to rural villages across Devon, southwest England. The main aim of this study is to find out whether delivering a physical activity programme (Devon Active Villages) to rural villages results in increased physical activity participation. Additionally the study will look at whether people feel more supported and find it easier to be active in their village after taking part in the physical activity programme. To evaluate the success of the physical activity programme, the study will involve a large postal survey within the villages receiving the intervention.

Who can participate?
Men and women aged 18 years and older, resident in one of the 128 selected villages and able to read and write in English. Anyone aged 18 years or over can participate, it does not matter whether they are healthy volunteers or whether they have a certain health problem.

What does the study involve?
Each selected village will be consulted on what types of activities they would like to be delivered in their village. The villages will then receive twelve weeks of subsidised sports and activities, as well as any necessary equipment. Local volunteers will be recruited to help run the activities. Each village will also be supported for twelve months following the intervention being delivered, and helped to sustain the activities in the long term. The intervention will be delivered in four phases, staggered over a two year period.
Postal questionnaires will be sent out to households across the 128 selected villages at five time periods, across a period of two years, because we will be measuring changes in your area over time. Households in the selected villages will be recruited at random to participate in the study. If you take part, you will receive a questionnaire in the post, as well as a participant information

sheet and a pre-paid envelope in which to return the questionnaire. One adult per household will be asked to complete the questionnaire. If there are multiple eligible adults in the household, an invitation to complete the questionnaire will be given to the adult who has most recently had a birthday. The questionnaire will ask about you (gender, age, height, weight, health etc.,), your physical activity behaviour, opinion on your local area, awareness of activity campaigns, and your feelings about being physically active. You may receive the questionnaire on more than one occasion and we would appreciate it if a member of your household fills out the questionnaire on each occasion.

What are the possible benefits and risks of participating?
There are no known risks to participants. Participants are made aware in the information sheet that their participation in the study is completely voluntary. The information provided will be treated in strict confidence in accordance with the Data Protection Act, and will only be used for statistical purposes. The benefits to participants are that they are given the opportunity to be a part of a study and have their say on the way physical activity interventions are delivered to rural communities.

Where is the study run from?
The study is being run from the University of Exeter, Exeter, UK. Villages will be recruited from across the county of Devon, southwest England.

When is the study starting and how long is it expected to run for?
The study started in April 2011 and will run till December 2012. Participants will be recruited for the questionnaire study at five time periods between March 2011 and February 2013.

Who is funding the study?
The Economic and Social Research Council (ESRC), the National Institute for Health Research (NIHR), and the College of Life and Environmental Sciences (CLES) at the University of Exeter.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
The Devon Active Villages Evaluation trial: A stepped wedge cluster randomised trial of a community-level physical activity intervention in rural Southwest England

Acronym
DAVE

Study objectives
It is hypothesised that community levels of physical activity participation will improve after each village receives the intervention. Intervention villages are hypothesised to have higher levels of physical activity participation when compared to control villages. It is also anticipated that changes will be observed in levels of social support, physical activity intentions, awareness and use of local facilities, and perceived village supportiveness of physical activity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Life and Environmental Sciences Ethics Committee at the University of Exeter, 01/03/2011

Primary study design
Interventional

Study design
Single-centre stepped wedge cluster randomised trial

Study type(s)
Quality of life

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

Interventions
During the DAVE study, the community-level physical activity intervention will be rolled out sequentially to 128 rural villages (clusters) over four time periods.

The evaluation will consist of data collection at five fixed time points (baseline and following each of the four intervention periods). The period in which the villages first receive the intervention will be randomly assigned, stratified by the seven regions of the county of Devon. The intervention will be fully implemented by the end of the trial, with all 128 villages receiving the intervention: 22 first receiving the intervention at period 2, 36 at period 3, 35 at period 4, and 35 at period 5. Each of the villages will receive the intervention for a 12-week period, and will then be followed-up for a further 12 months. The whole intervention will be rolled out over a three year period.

The intervention time period for villages in period 2 is April-June 2011, for period 3 villages is September-December 2011, for period 4 villages is April-June 2012, and for period 5 villages is September-December 2012. Period 1 is the baseline data collection period, carried out in all 128 villages in March 2011.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Community levels of physical activity, measured using the International Physical Activity Questionnaire (IPAQ) short form at baseline, and after each of the four intervention periods

Key secondary outcome(s)
1. Physical activity intentions
2. Habits and perceived social support for physical activity, measured using questionnaire items based on survey questions from an Australian cohort survey study
3. Awareness and use of local physical activity facilities, measured using questionnaire items based on survey questions found to have acceptable levels of test-retest reliability.

Measured at baseline, and after each of the four intervention periods

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Male and female, and must be aged 18 years or over, there is no upper age limit.
2. The participants in the trial can be patients, health volunteers, doctors, health professionals, there are no excluded professions
3. Residents of one of the 128 intervention villages

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Aged 17 or younger
2. The participants cannot live in a location that is not within one of the 128 intervention villages

Date of first enrolment
01/03/2011

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sport and Health Sciences
Exeter
United Kingdom
EX1 2LU

Sponsor information

Organisation
University of Exeter (UK)

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council (ESRC) (UK) - Building Clusters Award (RES-187-24-0002), as part of an ESRC CASE Studentship in partnership with Active Devon

Funder Name
National Institute for Health Research (NIHR) (UK) - Collaborations for Leadership in Applied Health Research and Care (CLAHRC)

Funder Name
University of Exeter Link Fund (UK)

Funder Name
College of life and Environmental Sciences at the University of Exeter (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/07/2014		Yes	No
Protocol article	protocol	01/08/2012		Yes	No