Evaluation of community level interventions to address social and structural determinants of health

Submission date 08/04/2008	Recruitment status No longer recruiting Overall study status Completed	Prospectively registered		
		[X] Protocol [_] Statistical analysis plan		
Registration date 10/04/2008		[X] Results		
Last Edited 13/04/2016	Condition category Other	[_] Individual participant data		

Plain English summary of protocol

Background and study aims

The aim of this study is to measure the effect and cost effectiveness of Well London, a complex 3.5-year intervention to promote healthy physical activity, healthy eating and mental health /wellbeing in 20 of London's most deprived communities.

Who can participate? Residents in the participating areas of London

What does the study involve?

The 20 boroughs each select two deprived communities as candidates, and one community is selected at random to receive the Well London intervention, while the other community receives no intervention (the comparison or 'control' community). The intervention communities participate in designing, delivering and evaluating interventions to meet their needs. Interventions are drawn from a set of possible projects. The exact mix is decided upon in each area depending on what local people identify as priorities and what facilities and services are already provided. Possible projects include improving public spaces to encourage physical activity, supporting local cultural projects, improving access to healthy food choices in the local area, and raising awareness of mental health. We compare physical activity, healthy eating and mental health/wellbeing between the intervention and control communities by carrying out surveys before the health promotion activities start and again after four years.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Massey University (New Zealand)

When is the study starting and how long is it expected to run for? March 2008 to December 2012 Who is funding the study? 1. Big Lottery Fund (UK) 2. The Wellcome Trust (UK) (grant ref: 083679)

Who is the main contact? Dr Martin Wall

Study website http://www.londonshealth.gov.uk/well_london.htm

Contact information

Type(s) Scientific

Contact name Dr Martin Wall

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers WT083679AIA

Study information

Scientific Title

A randomised cluster controlled trial of community level interventions to address social and structural determinants of physical activity, diet and mental wellbeing

Acronym WLRCCT

Study objectives

Are community designed interventions at Lower Super Output Area (LSOA) level effective in securing improvements in levels of healthy eating, healthy physical activity and mental health?

Ethics approval required Old ethics approval format

Ethics approval(s) University of East London Research Ethics Committee, 15/10/2007, ref: ETH/07/96/0 UEL

Study design Randomised cluster controlled trial

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) Community

Study type(s) Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Healthy behaviours related to diet, exercise and positive mental wellbeing

Interventions

Target number of participants:

In each wave of the adult survey (at the start and end of the project) there will be 4000 participants (100 in each of the 20 intervention and 20 control areas). In the adolescent survey there will be 60 children in each of the 40 areas in each wave.

Interventions:

Well London (WL) is the Greater London Authority's flagship project on health supported by NHS London and 20 primary care trusts (PCTs) and boroughs. The project commenced in March 2008 in 20 of the most deprived communities in London with £9.42 million funding from Big Lottery "Wellbeing" Fund (BLF) delivering complex interventions over 3.5 years to address poor diet, insufficient physical activity and poor mental wellbeing. Interventions are based on existing best practice, designed and implemented with community participation.

Initially two areas (LSOAs) in each of 20 London boroughs were chosen as being in the most deprived 10% of all London LSOAs using the Index of Multiple Deprivation. One of the two was then randomly chosen for interventions and the remaining area was left as control with no spending. The two areas do not adjoin each other to avoid any 'spill-over' of the intervention. The control cluster is therefore 'matched' to the intervention area in that it is in the same borough and that it is similarly deprived. Health indicators in matched clusters will be compared at start and end of WL. Quantitative surveys will take place in both intervention and control clusters to evaluate interventions and the approach taken to participatory design and provide evidence on appropriateness of extending this model to other deprived areas.

Interventions are drawn from a set of possible projects. The exact mix will be decided upon in each area depending on what local people identify as priorities and what facilities and services are already provided. The set of possible projects include:

1. Healthy Spaces a project to improve the quality of public space in the area to encourage physical activity

2. Active Living, residents will be provided with maps informing them of local resources for making healthy choices e.g. farmer's markets, open space

3. Be Creative Be Well, supporting and facilitating local cultural projects to foster social networks and social capital

4. Buywell, a set of interventions to improve access to healthy food choices in the local area

5. Changing Minds, people with experience of mental ill-health will be recruited to raise awareness of mental health and promote understanding of its impact

6. DIY Happiness, using humour and creativity and based on positive psychology theories activities will aim to reduce impact of stress and increase psychological resources

7. Eatwell aims to improve diet and nutrition by raising awareness of importance of diet to physical and mental health and making healthy eating easier and more attractive Full details of the projects are on the Well London website at http://www.londonshealth.gov.uk /well_london.htm.

The interventions are due to start in all intervention areas in 2008 and continue throughout the four year period with roughly equal spend on project activity in each year. The follow-up is a repeat of the adult and adolescent surveys at the end of the interventions in 2012. The surveys will be of a randomly selected sample of addresses within the intervention and control areas. We are not attempting in 2012 to re-contact those who took part in the survey in 2008.

Intervention Type

Behavioural

Primary outcome measure

Adult survey:

Changes in levels of mental health (MH), physical activity, healthy eating between baseline and follow up. MH is measured using the 12-item General Health Questionnaire (GHQ-12) and positive psychology scale. Also questions on social networks and social capital are drawn from the UK Government Harmonised question set on social capital. Physical activity is measured using the International Physical Activity Questionnaire. Diet is measured using questions from the Health Survey for England on items consumed in the previous 24-hour period. Other questions on healthy quality of life and demographic and social characteristics are also collected.

Child survey:

Adolescent questionnaire measures emotional behavioural status using 2001 Child Behaviour checklist, self -esteem will be measured using Rosenberg self-esteem scale, the Child Health and Illness Profile - adolescent edition will be used to measure overall health status and the Child's Attitudes to Physical Activity Scale will assess attitudes to PA. Again the measures will be taken at baseline and follow-up in control and intervention areas.

Secondary outcome measures

Questionnaires will not only measure levels of healthy behaviour around diet, physical activities and mental well being but perceived barriers or constraints to identify areas where resources can be targeted.

Overall study start date

01/03/2008

Completion date

01/12/2012

Eligibility

Key inclusion criteria

1. Adult survey, resident in a sampled address within intervention or control areas over age of 16, either sex

2. Child survey, resident of the area and at school participating in survey, between 13 and 16 years old, either sex

Participant type(s)

Other

Age group Mixed

Sex Both

Target number of participants 4000

Key exclusion criteria

1. No participants under 13

- 2. No one who lives outside of the area
- 3. No residents whose addresses have not been randomly chosen

Date of first enrolment

01/03/2008

Date of final enrolment 01/12/2012

Locations

Countries of recruitment New Zealand

United Kingdom

Study participating centre Massey University Auckland New Zealand 1010

Sponsor information

Organisation University of East London (UK)

Sponsor details

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Sponsor type University/education

Website http://www.uel.ac.uk/

ROR https://ror.org/057jrqr44

Funder(s)

Funder type Charity

Funder Name Big Lottery Fund - funding interventions

Alternative Name(s) BIG

Funding Body Type

Private sector organisation

Funding Body Subtype Other non-profit organizations

Location United Kingdom

Funder Name Wellcome Trust (grant ref: 083679) - funding evaluations and full randomised cluster trial

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype International organizations

Location United Kingdom

Funder Name University of East London

Alternative Name(s) UEL

Funding Body Type Private sector organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Funder Name University of Westminster (UK)

Alternative Name(s)

Funding Body Type Private sector organisation Funding Body Subtype

Universities (academic only)

Location United Kingdom

Funder Name London School of Hygiene and Tropical Medicine (LSHTM) (UK)

Funder Name Loughborough University (UK)

Alternative Name(s) Lboro

Funding Body Type Private sector organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

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?
<u>Protocol article</u>	protocol	28/06/2009		Yes	Νο
Results article	results	06/07/2012		Yes	No
Results article	results	02/12/2013		Yes	No