A sport-for-development intervention for the physical and mental health of young adolescents in Gulu, Uganda

| Submission date | Recruitment status | Prospectively registered | | |
|-------------------|----------------------------------|-----------------------------|--|--|
| 14/02/2012 | No longer recruiting | Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 19/03/2012 | Completed | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 28/02/2019 | Mental and Behavioural Disorders | | | |

Plain English summary of protocol

Background and study aims

Non-communicable diseases (NCDs) are a significant health problem throughout the world. They are of increasing concern in many low- and middle-income countries. The movement of people towards urban areas is thought to contribute to social, environmental and behavioural changes associated with NCDs. Physical activity (PA) has been found to have a positive effect on adolescent NCD risk factors, physical health (PH) and mental health (MH) disorders that may continue into adulthood.

Sport-for-development (SFD) programmes are being developed in numerous low- and middle-income countries throughout the world. Organisations delivering SFD interventions in post-conflict regions claim to increase levels of PA and have a positive effect on NCD risk factors, PH and MH. However, there is very little evidence to support these claims.

Gulu is a post-conflict zone in northern Uganda. It is likely to experience an increase in NCDs if current patterns in health care, PA behaviour, socio-economic development and urbanisation continue.

The aim of this study is to contribute to the evidence for SFD programmes in post-conflict settings using methods that are feasible in Gulu, Uganda. The primary research questions are:

- How do SFD programmes impact on PA levels?
- How do SFD programmes impact on PH (cardiorespiratory fitness, muscular strength, body composition)?
- How do SFD programmes impact on specific MH disorders (locally described depression- and anxiety-like syndromes two tam, kumu, par, ma lwor)?

Who can participate?

Approximately 10 primary schools in Gulu municipality will be randomly selected to participate in the study. To be eligible to take part in the study you need to be a healthy volunteer that is:

- Enrolled and attending P6 in one of the selected schools
- Aged 11-14 years

If you are eligible, you will be invited to take part in the PH and MH assessment. A randomly selected sample of the participants will also be invited to undertake PA assessment. You can choose to withdraw from the study at any time and will not be penalised in any way.

What does the study involve?

The study compares young adolescents who play football in the current season of a local SFD programme to those who do not participate. Registration for the SFD programme is voluntary. If you do not register you will be part of a comparison group (group 1). If you do register for the SFD programme and it is over-subscribed you will be randomly selected to either participate in the intervention (group 2) or be wait-listed for the next season (group 3). We will compare the PA, PH and MH of each of these groups before and after the SFD programme has been delivered. During the study, you will complete four tests that will take place during your sport and physical education lessons at school:

- Measurement of body height and weight using a tape measure and weighing scales;
- Measurement of muscular strength using the standing broad jump which involves jumping as far forward as possible from a standing start;
- Measurement of cardio-respiratory fitness using the "beep" test which involves walking and running for a period of up to 10-15 minutes;
- Measurement of mental health status using a questionnaire that asks about the signs and symptoms of 4 locally described syndromes (two tam, kumu, par, ma lwor) in the past 7 days.

You may also be asked to wear a PA measurement belt for 1 week. There is a small box attached to the belt that assesses your levels of PA. The belt and box are not harmful in any way. If you are chosen for the PA assessment, you should:

- Wear the belt everyday including weekends;
- Wear the belt all the time even when not wearing school uniform;
- Wear the belt when playing sport;
- Only take the belt off when washing or sleeping.

If you are chosen for the PA assessment, you should not:

- Take the belt off for anyone;
- Give the belt to anyone else;
- Open the small box on the belt;
- Use the belt for any other purpose.

A report that summarises the results of the study will be distributed throughout the community in Gulu. We also hope to publish the results in academic journals after the study has been completed.

What are the possible benefits and risks of participating?

The study will improve our understanding of how participation in organised SFD programmes affects adolescents in Gulu. It will contribute to improving future programme delivery. This will benefit the local youth and organisations active in the SFD sector in Gulu. You will not receive any individual reward for participating in this study.

There is a small risk that you will experience a negative emotional response to the MH questionnaire or physical injury during the PH tests. This will be monitored by trained personnel at the time of application and appropriate follow-up organised as necessary. Your results will be kept strictly confidential and only the researchers will have access to this information.

Where is the study run from?

Measurements will take place in approximately 10 primary schools within Gulu municipality. The intervention will be conducted at the main sports stadium (Pece Stadium).

When is the study starting and how long is it expected to run for?

Your PH and MH will initially be assessed at the end of term 2 of the academic year in 2010 (i.e. July 2010). The SFD intervention and PA assessments will take place during term 3 of the academic year in 2010 (i.e. September - November 2010). The PH and MH assessments will be

repeated at the end of term 3 of the academic year in 2010 (i.e. November 2010). At the end of the initial study there will be an extended follow-up period during which time the initial data analysis, report write-up and result dissemination will also take place. You may be asked to complete follow-up measures for PH and MH approximately 15 months after the SFD programme finished. This will take place during term 1 of the academic year in 2012 (i.e. March 2012).

Who is funding the study?

This study is funded by the personal scholarship of Justin Richards and the Department of Public Health at the University of Oxford, UK.

Who is the main contact? Dr Justin Richards justin.richards@dph.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Evaluating the impact of a sport-for-development intervention on the physical and mental health of young adolescents in Gulu, Uganda - a post-conflict setting within a low-income country

Study objectives

Community-based sport-for-development programmes positively effect the mental health (locally described depression and anxiety-like syndromes) and physical health (physical activity levels, cardiorespiratory fitness, muscular strength and body composition) of young adolescents in Gulu, Uganda.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Oxford Tropical Research Ethics Committee, 13 May 2010 ref: 18-10
- 2. Gulu University Institutional Research Committee, 06 July 2010 ref: GU/IRC/01/6/10

Study design

Multi-centre, assessor-blinded, randomised controlled trial with wait-listed control nested within a longitudinal cohort study and triangulated by a cross-sectional validation study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Physical activity, physical fitness, cardiorespiratory fitness, muscular strength, mental health, non-communicable diseases

Interventions

Current interventions as of 03/09/2012:

Assessors are masked to registration for the intervention and subsquent computer generated allocation into three parallel groups.

Intervention: The Gum Marom Kids League is a community based sport-for-development programme in Gulu, Uganda. It comprises of a 11 week football league with weekly training sessions (approximately 1.5 hour) and games (approximately 1 hour) delivered by trained coaches.

Control 1: No treatment (wait-listed for next "season" of the intervention).

Control 2: No treatment (not registered to participate in the intervention).

Initial follow-up assessment will take 3 weeks and will take place immediately after the completion of the intervention. It is anticipated that final follow-up for a sample of the participants will take place 15 months after the completion of the intervention.

Previous interventions until 03/09/2012:

Intervention: The Gum Marom Kids League is a community based sport-for-development programme in Gulu, Uganda. It comprises of a 11 week football league with weekly training sessions (approximately 1.5 hour) and games (approximately 1 hour) delivered by trained coaches

Control: No treatment (wait-listed)

Initial follow-up assessment will take 3 weeks and it is anticipated that final follow-up for a sample of the participants will take place 15 months after the completion of the intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Cardiorespiratory fitness measured using the standardised multi-stage fitness test ("beep test") at baseline and at 4 months (i.e. after the intervention). Long term follow-up measures planned for a sample of the participants at 15 months post intervention.
- 2. Muscular strength measured using the standing broad jump at baseline and at 4 months (i.e. after the intervention). Long term follow-up measures planned for 15 months post intervention.
- 3. Body composition measured using body mass index (BMI)-for-age at baseline and at 4 months (i.e. after the intervention). Long term follow-up measures planned for a sample of the participants at 15 months post intervention.
- 4. Mental health measured using the Acholi Psychosocial Assessment Instrument (APAI) to assess local depression-like (two tam, kumu, par) and anxiety-like (ma lwor) syndromes at baseline and at 4 months (i.e. after the intervention). Long term follow-up measures planned for a sample of the participants at 15 months post intervention.

Secondary outcome measures

Physical activity measured using accelerometers on a series of subjects for a duration of 1 week during the intervention.

Overall study start date

12/07/2010

Completion date

01/04/2012

Eligibility

Key inclusion criteria

- 1. Healthy and able-bodied young adolescents
- 2. Enrolled in P6 of a primary school within Gulu Municipality
- 3. Aged between 11-14 years
- 4. Informed consent obtained

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

1500

Key exclusion criteria

Pre-existing illness or disability

Date of first enrolment

12/07/2010

Date of final enrolment

01/04/2012

Locations

Countries of recruitment

England

Uganda

United Kingdom

Study participating centre University of Oxford

Oxford United Kingdom OX3 7LF

Sponsor information

Organisation

University of Oxford (UK)

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Sponsor type

University/education

Website

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ROR

https://ror.org/052gg0110

Funder(s)

Funder type

University/education

Funder Name

University of Oxford

Alternative Name(s)

University in Oxford, Oxford University, , Universitas Oxoniensis

Funding Body Type

Government 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? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 18/06/2014 | 28/02/2019 | Yes | No |