

Form: Project Approval

Forms received 02/09/2010 in vigorous - scissors portal for the Regional Committees for Medical and Health Research Ethics (REK) on; helseforskning.etikkom.no

2010/2385-1

Summary

1. General information

A. Project Title

Project Title: Soccer, Zumba and health

Scientific title: Physiological

Project : Svein Barene

Research coordinator: University of Nordland, Norway (UIN)

Initiator : Project or Research Manager (Research Contributions)

Education Project:

Study : Study of professional knowledge

Level : PhD

Norwegian title Soccer, Zumba and health

Scientific title: Physiological, psychological and sociological health effects from soccer and Zumba, respectively, in a worksite .

B. Project leader

Name: Svein Barene

Degree: Master of Science

Clinical expertise:

Position: PhD student

Main work: UIN

Work Address: Centre for Performance

Zip 8049

Location: Bodø, Norway

Phone: 75517564

phone:

E - mail address: svein.barene@hibo.no

C. Research responsible

Research coordinator is: Institution or other legal person

Institutional / legal person: UIN

Street Address / PO Box: v/Centre for Performance

Zip: 8049

Location: Bodø

Contact: Svein Barene

Position: PhD student

Phone: 75517564

Mobile Phone: 95258477

E - mail address: svein.barene@hibo.no

D. Project location

Initiator of the project: Project or Research Manager (Research Contributions)

Cooperation with foreign countries: Yes

Part of an international multicenter trial: Yes

Independent data collection abroad:

Education Project/PhD project: Yes

Study: Study of professional knowledge

Level: PhD

Related research: Yes

Project Title: Soccer and Health

Alternatively REK No:

Any remaining case number in REK:

E. Researchers

Name: Jan Selmer Methi

Position: Associate professor

Institution: UIN

Academic degree: PhD

Project Role: Supervisor

Name: Peter Krustrup

Position: Lecturer

Institution: University of Copenhagen, Department of Sports (Denmark)

Academic degree: PhD

Project Role: Supervisor

Name: Andreas Holtermann

Position: Senior Researcher

Affiliation: National Research Centre for the Working Environment, Copenhagen (Denmark)

Academic degree: PhD

Project Role: Supervisor

Name: Ole-Lars Brekke

Position: Consultant /1. Assistant Professor

Institution: Nordland Hospital, Department of Laboratory Medicine/University of Tromsø (Norway)

Faculty of Health Sciences, Institute of Medical Biology

Degree: Dr.med

Project Role: Collaborator

2. Project Information

A. Background and Purpose

Project description by the Project Manager:

At the University of Copenhagen previous studies have shown that soccer is more health beneficial compared with for example running and strength training. In this study, we want to conduct an intervention study among a working population in Bodø, i.e. 12-week training period of soccer and the Latin- inspired dance fitness Zumba, respectively. The different training groups will be tested for physiological parameters before and after the training period in order to compare the effects of the two training forms. In addition to the two intervention groups we will establish a control group who will only participate in the tests. Furthermore, we wish to highlight experiences that occur among employees through participation in training activities outside working hours.

B. Research Data

New health information: Yes

Specify the types of health information: VO₂ measurements, body fat percentage, bone density, blood samples (lipids-/lactate measurements), blood pressure measurements

Human biological material: Yes

Data collection: The material will be collected during the project period.

C. Research Methods

The project is: Both quantitative and qualitative

Intervention: Yes

Clinical examination: Yes

Questionnaire: Yes

Interview: Yes

Audio recording: Yes

Observation: Yes

Film / Video: Yes

Photograph: Yes

Academic and scientific justification for the choice of method:

In an activity-theoretical perspective, one can see any phenomenon from a quantitative and a qualitative conditions (Marx , 2008). In this study, we want to use both quantitative and qualitative methods. The quantitative data has its own form of knowledge, and often expressed in proportional sizes. They reproduce a greatly reduced relationship that exist in reality, but are not irrelevant. It is possible to understand that a man is subjected to a special controllable physical activity may have changed his muscle mass and oxygen consumption for given conditions. However, it is not possible to deduce from this that the wellness increases. This requires a qualitative approach. In the qualitative approach, the quantitative data lie in the background. The qualitative study will be looked at how physical activity turns out, and is expressed by the participants themselves. It is their experience – and the researchers' understanding of it, that gets attention. For a coach, we assume that both of these conditions are important to understand. The quantitative data provides some facts about the effects that come out of these activities, but provides no deeper understanding of what they actually represent. In this study, we will try to look at the activities from a phenomenological perspective, and attempt to create

understanding (from my position as coach) by reflections upon my observations. We will divide this work into three phases:

Phase 1: The initial phase (before intervention).

Method: Interview.

In this phase we will randomly select 5-6 subjects from each intervention group to interview.

Phase 2: Intermediate phase (during the intervention).

Method: Questionnaire and field interviews.

Subjects will initial to the training be given a questionnaire consisting of four new closed questions which are prepared on the basis of field interviews in the previous exercise. During the training sessions, I will conduct field interviews with 2-4 subjects who are based in spontaneous situations that arise.

Phase 3: The final phase (after intervention).

Method: Interview. The same subjects who were interviewed in Phase 1 will at this stage be invited to a new interview, which will focus on the experience and lessons learned through participation in the respective intervention groups.

The quantitative data will be conducted in a controlled, cluster - randomized design, in which groups of employees who have a work community, e.g. the same working hours, will be drawn randomly to one of three exercise groups;

Group 1: Soccer (3 x 60 min) - 30 people playing soccer 2 x 30 minutes three sessions per week for 12 weeks. The soccer training will be organized by dividing into teams consisting of 4-8 players, and will be played on small courts either outside or inside. The training intensity is measured with heart rate monitors and movements registered by GPS or time-motion .

Group 2: Zumba (3 x 60 minutes) - 30 employees will be perform Zumba at "Friskhuset" 60 minutes three sessions per week for 12 weeks. The Zumba training will be conducted with certified instructor in a dance-room. The training intensity is measured with heart rate monitors.

Group 3: Control group: - 30 employees receive no training, but will be offered health consultation based on information from the physiological tests.

Health indicators :

Health effects: Body weight, body fat percentage, and bone density, blood pressure, blood glucose, cholesterol, physical capacity (including aerobic endurance, strength, flexibility, balance ability and reaction time).

Effects on absenteeism, effects on employees experienced psychological work environment.

D. Selection

General Population: Yes

Control group (s): Yes

Specify who should be included in the control group(s): A random sample from the companies involved.

Justify the choice of control group(s): In order to have a basis for comparison in relation to any effects of training in the two training groups.

E. Scope

Norway: 80-130

Explain and justify the project scope: Refer to "Technical and scientific justification for the choice of data and method " and the attached protocol.

2E. Biobank

2C. Biobank

A.

New specific research biobank: Yes

Biobank name: Soccer, Zumba and health

3. Consent and Privacy

A.

B.

Consent obtained: Yes

For what data should consent be obtained? All

Specifically actively informed written consent: Yes

Elaborate how to ensure a free and informed consent and explain any deviations from recommended procedures: It will be held an information meeting with the employees of the company, and it is essential that all participation in the intervention study is voluntary.

C.

4. Ethical assessment of the advantages and disadvantages

A. Benefits

All participants: Yes

Specify the advantages: Participation in one of the training groups will lead to increased physical activity for participants, and you will most likely achieve better physical capacity.

Groups of people: Yes

Specify which groups: training groups, staff groups engaged in joint training activities that represent something other than the work you normally do together.

Specify the advantages: Interaction and cooperation which are perceived as enjoyable.

Increases of the community wellness, team -building.

Society: Yes

Specify the advantages: Focuses on physical activity and health in a community perspective.

Science: Yes

Specify the advantages: Documentation of physiological, psychological and sociological effects of two different training methods.

B. Disadvantages

Each project participant: Yes

Enter the disadvantages: Can cause minor sport related injuries, such as ankle twisting, etc., but from studies in Denmark, this occurs to a small extent. There will obviously be a discomfort associated with venipuncture, but this is considered a minimal problem and without risk of complications or accidents. Running test will of course entail degree of fatigue towards the end.

C. Measures

Elaborate the safety of the participants in the research project: Participants will be closely monitored throughout the intervention period, and the security of training will be addressed in a proper manner. In the event of any damage, the involved will be offered emergency medical treatment. Warm-up will be conducted so that participants are well prepared to prevent injuries, etc.

D. Ethical considerations

Describe your trade-off between advantages and disadvantages and give your reasons for why you believes it is prudent to undertake the project:

It is not considered to be any risks of participation in the project beyond regular physical activity time .

5. Safety, interests and publication

A. Personally identifiable information

Personal information recorded in the project is directly personally identifiable: Yes

Name, address, or date of birth: Yes

11- digit identity number: Yes

B. Internal Control and Security

Physically isolated computer related activities: Yes

Video recording / photography: Yes

On personal computer (PC): Yes

Audio recording: Yes

On PC: Yes

Manual / Paper: Yes

Linking Key and data stored separately from each other: Yes

Background information (place of residence, occupation , etc.) are kept separate from other information: Yes

Password Protected storage: Yes

Incarcerated storage: Yes

Explain in more detail how personally identifiable information is protected from unauthorized access: All data will be locked in a safe for safe storage.

C. Insurance Coverage for participants

Insurance is considered unnecessary: Yes

Explain why it is considered unnecessary insurance for research participants:

D. Assessment of other agencies

Private institution: Yes

E. Interests

Funding: The project is a cooperation between Bodø, Nordland Hospital, Friskhuset, University of Copenhagen, and the National Centre for our work environment (Copenhagen).

Remuneration to the institution:

Fees manager/staff:

Compensation for research participants:

Any conflicts of interest for the project manager/staff: No, there are no such constraints.

F. Publication

Explain how the results should be made publicly available:

The results will be published in recognized international journals.

G. Public disclosure

H. Timeframe

Project Start date: 02/09/2010

Project End Date: 19.11.2015

After the end of year data de-identified: Yes

Explain further handling of data after project completion: Data will be stored in locked safes.

6. Appendix

1 Protokoll_SBA020910.pdf - Research Protocol - 03.09.10

2 Spørreskjema_020910.pdf - Questionnaire - 03.09.10

3 Samtykkeskjema_SBA020910.pdf - Consent form - 03.09.10

4 Intervjuguide_010910.pdf - Interview Guide - 02.09.10

5 Infoskriv_fysisk activity and arbeid.pdf - Request for participation - 02.09.10

6 screening_230610.pdf - Sreeningskjema - 02.09.10

7. Legal notice

A.

I declare that the project will be conducted in accordance with applicable laws, regulations and Guidelines: Yes

I declare that the project will be conducted in accordance with the information provided in this application: Yes

I declare that the project will be conducted in accordance with any conditions of approval given by the IEC or other authorities: Yes