**Title:** Development of an Exergame to Deliver a Sustained Dose of High-Intensity Training: Formative Pilot Randomized Trial

**Document:** Study Protocol

**NCT number:** N/A

**Date:** 19/03/2018

**Development of the Game and Intervention**

During the preintervention period, regular focus groups comprising in-house participants, computer programmers, and exercise scientists with specialisms in delivering HIT were held. Together, we explored opportunities to gamify HIT protocols. Boxing was an obvious theme for gamification as it involves high-intensity exercise, and the subculture already exists within the target population of lower working-class males of the North-East of England. The complete set of hardware used in the trials comprised a single computer with a dedicated graphics card (GeForce GTX 960), two standard 23-inch monitors, two Kinect for Windows sensors, four wrist-mounted wireless inertial measurement units (developed in-house to reduce latency in the Kinect datastream), and two wireless chest-worn heart-rate monitors (Polar RS400, Polar Electro Oy, Kempele, Finland). In addition, participants wore boxing-specific resistance bands (ShadowBoxer Pty, Australia) to increase levels of exertion and reduce eccentric muscle contractions during the deceleration phase of punching. The movement data from the sensors were streamed to a gaming engine via a User Datagram Protocol with a latency of approximately 15 ms. Input from the skeletal tracking module of the Kinect system and inertial measurement units were converted to a digital avatar using purpose-written functions to convert each body segment long-axis (19 in total) into three-dimensional quaternions. The C# programming language was used throughout to create scripts for gameplay.

Commercial games are primarily designed for entertainment and recreation for younger populations and tend to have colorful and visually busy game and user interfaces. Furthermore, commercially available games are mostly designed for enjoyment and not based on basic exercise principles. For games to promote beneficial changes in health, they need to engage physiological systems in a meaningful manner that is relevant for the function being trained. Our philosophy was to ensure that the gameplay was simple and, where possible, true to the rules of boxing. Each avatar was assigned collision objects with inertial characteristics on the trunk, head, and hands, thus enabling the physics engine to superimpose realistic joint movements in response to being hit. As in real boxing, the primary mechanism for scoring was to successfully land a punch on either the trunk or head of the opponent. The number of points awarded per punch was the product of the current heart rate (expressed as a percentage of maximal) and speed of impact ($ms^{-1}$). Thus, for example, a punch landing to the head with a relative speed of 9 $ms^{-1}$and at 95% of maximal heart rate (ie, 95% HRmax) was awarded 8.55 points (ie, 9 x 0.95). Each participant was provided with biofeedback in the form of a partial arc positioned around the opponent's head; the angle subtended by this arc was linked to the current heart rate.

For example, when player 1 was working at 50% of maximal heart rate, an arc of $180^{o}$ was displayed around the head of player 2. The players were made aware that the angle of the arc was proportional to their current training intensity, which in turn contributed strongly to punch power and points scoring. They were also aware that large global displacements of their center of mass (eg, bouncing up and down) would increase this intensity but with a lag of approximately 20 to 30s. This arc was visible in their monitor only and was active throughout the exergaming session (ie, during both repetitions and rest), essentially allowing the participants to self-regulate training intensity per the oncoming requirements of the game. Although we kept on-screen text to a minimum, we elected to display a countdown timer during some periods. These were during the final 30 s of active recovery to encourage the elevation of training intensity in preparation for a repetition and during the latter 10 s of each repetition to encourage all-out punching right up until the bell. Following preliminary tests, we removed the ability to block punches as this was observed to be energetically undemanding; thus, the only forms of defense were to attack before being hit or to dodge the oncoming punch using whole body movements. For similar reasons, we limited the periods of allowable close-up punching. Specifically, after 1 s of close-up punching, the referee interrupted the fight and ordered both participants to race back to their respective corners (ie, 3 m

backwards of backwards stepping). The winner of each mini race received an additional 50 points; equivalent to approximately 6 to 7 well-timed punches. After several iterations of observing kinematics, heart rates, and tactics during gameplay, we prepared the exergaming system (ie, both hardware and software) for use in the target settings.

## Participants

We conducted a 6-week exploratory controlled trial designed to assess the fidelity of the game in terms of delivering the intended training stimulus and to examine the effect of the intervention on selected health outcomes. As appropriate for an exploratory trial, we did not conduct formal sample size estimation a priori, rather the CIs would be used to inform future trials. Men are commonly referred to as a hard-to-reach population to engage in health promotion activities, where a targeted recruitment approach at locations predominantly attended by men may facilitate uptake of participants. Therefore, to maximize recruitment within our intended population, relevant gatekeepers were approached at institutions positioned within regions of social deprivation. Thus, two settings used for recruitment and the trials were a social club and mosque, both situated within deprived regions of Middlesbrough, United Kingdom (TS1 and TS4). Recruitment in the social club relied heavily on the gatekeeper (club secretary), whereas uptake of South Asian men from a local mosque was more straightforward; all 9 mosque participants were recruited from a single demonstration (and we had similar experiences in previous iterations). Presumably, the intervention was culturally salient in this population; the North of England has developed some famous prominent Muslim boxers (eg, Amir Kahn and Naseem Hamed) in recent years, and when delivered in the safe form, was acceptable to the respected leaders of the religious groups (ie, the Imam of the mosque). A total of 24 males were recruited into the trial using relevant gatekeepers at institutions positioned within regions of social deprivation. Two recruitment drives (October 2014 and February 2015) took place, and these involved live demonstrations of the technology followed by word-of-mouth and snowballing approaches. The exergaming system was important in this recruitment process because it provided something tangible and interesting to engage potential participants.

Inclusion criteria were deliberately broad to maximize recruitment, that is, apparently healthy, as defined by ACSM guidelines and in the age range of 18 to 55 years. Participants were given a £15 shopping voucher upon completion of follow-up measures (week 7) irrespective of their adherence to the intervention protocol or group allocation. The intervention took place from November 2014 to December 2014 (social club) and March 2015 to April 2015 (mosque). Postcode data were analyzed to match against indices of multiple deprivation in lower-layer super output areas to check whether the cohort fell within our target population.

A third-party minimization process using baseline measures of age, waist circumference, and predicted maximum oxygen consumption ($VO_2$ max) was used to remove bias in group allocation. The control group was instructed to maintain their current physical activity levels and inform the researchers should any changes arise during the intervention

To explore perceptions of the exergame and the HIT regime, semistructured interviews were conducted with 5 intervention participants following the 6-week training period, which were analyzed semantically. The study was approved by the ethics committee of Teesside University, United Kingdom, and written informed consent was obtained from all participants.

## Measures

All measures were assessed pre and post intervention. Blood pressure was collected on the left arm positioned at heart height with the subjects in a seated position by an automatic upper arm blood pressure monitor (Omron MX13). Measures were made at least three times at 3-min intervals,

where an average of the two lowest measures was used for analysis. Waist circumference was measured using the World Health Organization guidelines. Predicted $VO_2$ max was obtained by performing a submaximal 8-min ramped step test. Heart rate response (Polar T34; PolarElectro OY, Kempele, Finland) and simultaneous breath-by-breath expired gas were collected using a portable indirect calorimeter (Cosmed K4 b2; Rome, Italy), calibrated per the manufacturer's guidelines. Individual HRmax was estimated and plotted against $VO_2$ data for the determination of predicted $VO_2$ max.

**Intervention Delivery**

Evidence recommends a minimum duration of 12 weeks for a HIT protocol to promote favorable changes in blood pressure and anthropometric measurements of obesity. However, a 6-week intervention was selected, as a minimum of 13 sessions (0.16 work/rest ratio) is sufficient to elicit moderate improvements in $VO_2$ max in sedentary individuals. Additionally, there is still ambiguity regarding the optimal work-to-rest ratio when designing HIT interventions, particularly in populations with varied age, baseline fitness, and training experience. Therefore, longer duration HIT models (1-4 min) were deemed unsuitable for our target population. Furthermore, minigames (such as the current exergame) have short life spans, where adherence to a longer intervention (eg, 12 weeks) may diminish over time and influence health outcomes. This was evident from a 12-week pilot study (unpublished data) using an exergame in the same population that saw attendance drop from 53% during week 2 to 16% during week 12.

Participants allocated to the intervention group were invited to attend three sessions of exergaming per week. At the beginning of the exergaming session, participants were required to complete a 6-min structured warm-up consisting of a series of exercises on a 210 mm step until both participants reached ~70% HRmax. Session workloads with volumetric progression were set automatically once the user's identifying information was entered. The session workloads were 120s-, 150-s, and 180-s of work during weeks 1 and 2, weeks 3 and 4, and weeks 5 and 6, respectively.

To avoid staleness, the repetition lengths (10, 20, or 30-s) were randomly selected at the beginning of each round. We set the work-to-rest ratio at 1:4, and thus, the respective repetitions were followed by 40, 80, or 120-s of active recovery. Participants were instructed to perform the repetitions at an intensity ≥85% HRmax. Each exergaming session took approximately 30 to 40 min to complete, including equipment set-up, warm-up with additional enjoyment, and task immersion questionnaires upon completion of the HIT bouts (not reported here). Heart rate responses were taken within repetitions and therefore, did not include any of the recovery period. This, therefore, avoided an overestimation of physiological load, which can occur when heart rate continues to rise after exercise cessation.

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**Statistical Analysis**

Exergaming session attendance was calculated using descriptive statistics. Training data (heart rate [repetition mean and peak], rating of perceived exertion [RPE]) were analyzed using a mixed linear model with a random intercept (Statistical Package for the Social Sciences [SPSS] version 23 [IBM Corp]).

This approach enabled us to calculate (1) the within-participant variability in the training dose, expressed as an SD; (2) the effect of HIT repetition duration (entered as a fixed effect) on heart rate and RPE; and (3) the change in heart rate and RPE across the 6-week HIT intervention, with session number (1-18) entered as a fixed effect. A priori, we defined a minimal practically important difference (MPID) in training heart rates as two percentage points, given that when training at high-intensity, this difference influences the adaptive response.

The MPID for RPE was set at one arbitrary unit (AU) on the Borg CR10 Scale, representing a full increment change on the scale. Inferences were then based on the disposition of the 90% confidence limits (CLs) for the mean difference to these MPID; the probability (percent chances) that differences in heart rate and RPE between HIT repetitions of different durations or across the 6-week intervention were substantial (>2 percentage points, >1 AU) or trivial was calculated as per the magnitude-based inference approach described by Batterham and Hopkins, an approach that has been advocated within user research.

These percent chances were qualified via probabilistic terms assigned using the following scale: 25 to 75%, possibly; 75 to 95%, likely; 95 to 99.5%, very likely; and >99.5%, most likely. To determine the magnitude of the within-participant variability in our training heart rate and RPE, the values were doubled and then interpreted against aforementioned MPID. All training data effects were evaluated mechanistically, whereby if the 90% CL overlapped the thresholds for the smallest worthwhile positive and negative effects, the effect was deemed unclear. The effect of HIT on our outcome measures was determined using a custom-made spreadsheet, with the baseline value of the dependent variable used as a covariate to control for baseline between-group imbalances. Following this, standardized thresholds for small, moderate, and large changes (0.2, 0.6, and 1.2, respectively) derived from between-subject SDs of the baseline values were used to assess the magnitude of all effects, with magnitude-based inferences subsequently applied. Here, all inferences were categorized as clinical, with the default probabilities for declaring an effect clinically beneficial being <0.5% (most unlikely) for harm and >25% (possibly) for benefit.

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**Document:** Informed Consent Form

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# INFORMED CONSENT FORM

**This information will be treated as confidential and only members of staff employed by Teesside University, Sport and Exercise section, will have access.**

**NAME** _____ **D.O.B.** _____

**Title:** A high-intensity, low-volume boxing exergame intervention to target cardiovascular health outcomes in males.
**Dates:** February 2015 – May 2015
**Researcher:** Tom McBain
**Supervisor:** Prof. Iain Spears

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1. I confirm that:
   - I am willing to take part in the above research project as a volunteer participant;
   - I have had no significant illness since my last medical examination;
   - I have had my attention drawn to the guidelines for research involving human participants;
   - Any questions I had about the study, or my participation in it, have been answered to my satisfaction.
2. I understand that:
   - The researcher will explain the nature and purpose of each data collection session and will inform me of any foreseeable risk to my health as a result of my participation;
   - I am free to withdraw from the study at any time without the need to give reason;
   - I have to terminate any physical activity if the researcher in charge feels it is advisable to do so;
   - I will inform the researcher in charge of any permanent and/ or temporary medical condition from which I am suffering or have suffered recently, which might be made worse by physical activity participation;
   - I agree to attend each and every physical activity/ testing session in a fully energised and hydrated state and to let the researcher know immediately if this is not the case;
   - I agree to my data being stored and used for the purpose of publication of the study;
   - In accordance with the 1998 Data Protection Act my data will be anonymised and stored securely;
   - In accordance with the 2004 Human Tissue Act any human tissue samples (blood, saliva) will be disposed of within 24 hours.
3. I agree to advise the researcher within 48 hours of any adverse effects that could be related to the research activities undertaken. Furthermore, I authorise the researcher in charge to inform my general practitioner should they feel that any significant untoward event occurs during or after the practical session, which might be a result of my participation.

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**SIGNATURE** (participant) _____ **DATE** _____

**SIGNATURE** (researcher) _____ **DATE** _____

**EMERGENCY CONTACTS**

**GP NAME** _____

**ADDRESS** _____

**TELEPHONE** _____

**NEXT OF KIN** _____

**ADDRESS** _____

**TELEPHONE** _____