



# EuroFIT

## Ethical review and approval for SitFIT study\*

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University of Glasgow	Coordinator
PAL Technologies Ltd	Beneficiary
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Norges Idrettshogskole	Beneficiary
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The University Court of The University of Aberdeen	Beneficiary
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The University of Edinburgh	Beneficiary

\*Public version for website distribution

## **Ethical review and approval for SitFIT study**

### **1 Introduction**

EuroFIT aims to attract men to lifestyle change through the personal connection and loyalty to the football clubs they support. Social innovation will be used to change physical activity and sedentary behaviour, specially targeting low-SES groups.

The overall goal of WP1 ‘Changing sedentary behaviour’ is to identify best practice for improving sedentary behaviour in inactive men. A key aspect of WP1 is the development of a novel device called ‘SitFIT’ by partner PAL Technologies Ltd. (PAL). The SitFIT device builds on the existing technology of the ‘activPAL’ device but in addition provides real time feedback on sitting time, standing time and stepping time to the wearer of the device. As part of WP1, the reliability and validity of the SitFIT device will be tested. Focus groups of users will provide feedback to the developers regarding the display functions of the SitFIT device. This deliverable covers the ethical approval required for testing the reliability and validity of the SitFIT device by end users and the associated focus group discussions.

### **2 Background**

EuroFIT will develop and validate a social innovation to support behavioural change to improve men’s health. Part of the innovation is to reduce sedentary behaviour. WP1 will identify best practice in interventions, strategies, and techniques for improving sedentary behaviour in inactive men. In addition, a novel low-cost pocket-worn device (SitFIT) with an integrated display will be developed to accurately and objectively measure daily sedentary behaviour and physical activity, and provide real-time feedback to enable prompts for and self-monitoring of behaviour change.

The SitFIT device builds on the existing technology of the ‘activPAL’ device, developed by partner PAL. The activPAL device is an inclinometer that measures posture. The activPAL device does not provide real time feedback to the user - data collected are only available after being downloaded to a computer. In contrast, the SitFIT device will provide real time feedback on sitting time, standing time and stepping time to the wearer of the device. The SitFIT device will also be able to communicate with mobile devices, such as smartphones and tablets.

The reliability and validity of the SitFIT device in measurement of sedentary behaviour and physical activity will be determined as part of WP1. In addition, the most useful type(s) and format(s) of feedback/user interaction from the SitFIT device for the facilitation of behaviour change will be investigated through focus groups. Ethical review and approval, as described in this deliverable, is fundamental for the activities required to achieve these objectives. Outputs from these initial assessments of the SitFIT device will be used to inform the design and evaluation of a simple intervention, incorporating behaviour change techniques, supported by self-monitoring feedback from the SitFIT device to reduce sedentary behaviour and increase physical activity, carried out as part of WP1. A small randomised controlled trial will be carried out in WP1 to determine if the SitFIT device is useful to participants who are trying to ‘sit less’.

Deliverable D1.1 does not rely on direct input from any other WPs. The achievement of the objectives and deliverables of WP1 will be used to inform the EuroFIT programme design (WP3) and in turn the protocol and delivery of the randomised trial (WP4 and WP5).

### **3 Approach**

All investigations led by UK universities involving data from human participants require approval by an appropriate Ethics committee. Ethical approval was sought from the Ethics Committee at the University of Glasgow Medical Veterinary and Life Sciences College.

## 4 Results

An application detailing the planned research was drafted by the WP1 team, including a description of the proposed research, study design and methodology, sample size, recruitment, consent, confidentiality and risk/potential benefit to participants. The application was submitted to the Ethics Committee for approval.

Ethical approval was received from the University of Glasgow Medical Veterinary and Life Sciences College Ethics Committee for the “Development and validation of the SitFIT: a pocket device to measure and provide feedback on physical activity and sedentary behaviour”

A subsequent amendment to the application was made to enable use of a smartphone app to monitor behaviour during a 7-day activity monitoring period to facilitate development of the MatchFIT app in WP2. The amendment was approved on 8<sup>th</sup> January 2014.

## 5 Impact

Ethical review and approval for the proposed work now allows the reliability and validity of the SitFIT device for measuring sedentary behaviour and physical activity to be determined, as well as the most useful type(s) and format(s) of feedback/user interaction from the device. Results from these initial assessments of the SitFIT device, reported in D1.4, will be used to design a simple intervention, incorporating behaviour change techniques, supported by self-monitoring feedback from the SitFIT device to reduce sedentary behaviour and increase physical activity. This intervention will be tested in a small randomised controlled trial, the results of which will also be reported in D1.4.

The SitFIT study, alongside the best practice outputs of WP1, will help the consortium decide on how best to use the SitFIT device in the full trial and intervention (WPs 3, 4 and 5).

## 6 Conclusion

Ethical review and approval for the SitFIT study under WP1 has been completed, so that the SitFIT study can now be carried out.