# R18

| Hub: London | Host University: LSHTM |
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| Supervisor: Elizabeth Williamson<br>Elizabeth.Williamson@lshtm.ac.uk | Co-supervisors: Henry Potts (London Farr/UCL Institute of Health Informatics) |
| Is the project clinical or non clinical? Non clinical | |
| Title of PhD project: Design of trials for health-related smartphone apps | |

**Background to the project**
Recent years have seen a huge expansion in the number of health-related mobile apps. These apps span a wide range of health arenas, with apps aiming to increase physical activity (e.g. Zombies, Run!), reminding patients take their medication at the correct time (e.g. MediSafe), supporting efforts to quit smoking (e.g. Butt Out), and helping patients track their own symptoms to better manage chronic conditions (e.g. Diabetes Tracker).

Mobile apps are rarely subjected to the same rigorous evaluation that other medical interventions receive. In particular, few health-related mobile phone apps have been assessed using a traditional randomised trial. The NHS is currently developing an app approval system and is debating what evidence will be required for different levels of certification, although it is expected trial evidence will not be required for the lowest level of approval, but will be for the highest level.

The absence of rigorous trial evaluation is in part due to methodological challenges:(1, 2) good app development follows an iterative design process, with updates reflecting knowledge gleaned from how current users navigate and use the app, thus it is difficult to define a "finished" product to include in a traditional trial. However, the use of A/B testing, with many similarities to trial methods, is common.

A second methodological challenge relates to the choice of control. Participants in a trial of an app available for general download who are randomised to the control arm will be able to obtain the app outside the trial, thus adherence to the randomised arm is likely to be low. One solution is to compare the full app to a minimum viable version, *i.e.* a reduced version of the app without the "active" ingredient. However, the ability to develop such a alternative depends on understanding the mechanisms that are expected to underlie any health-related effects of the app.

**What the studentship will encompass**
This project will explore issues of trial design when the intervention is a health-related smartphone app. The studentship will explore novel trial designs to handle the evolving nature of the intervention itself, drawing on adaptive trial designs and Bayesian methods; compare A/B methods to traditional clinical trial designs; and consider issues of how best to select a control arm or to identify what "ingredients" of an app are efficacious. A number of real examples will be used to evaluate different design options. We have the opportunity to link with the NHS app approval pilots and with a number of app developers in this area, including the makers of Zombies, Run!, and Thrive and Mindlife UK, two developers of e-mental health apps.

**Detail of supervision, including the roles of any named co-supervisors**
Dr Elizabeth Williamson is a methodological biostatistician with interests in trial methodology, and will act as the primary supervisor. Dr Henry Potts is a health informatician and statistician with close links with relevant app developers and a wide range of experience in the development and evaluation of patient-facing health technologies like apps.


1. Murray E, Hekler EB, Andersson G, Collins LM, Doherty A, Hollis C, et al. Evaluating Digital Health Interventions: Key Questions and Approaches. Am J Prev Med. 2016;51(5):843-51.
2. Murray E, Khadjesari Z, White IR, Kalaitzaki E, Godfrey C, McCambridge J, et al. Methodological challenges in online trials. J Med Internet Res. 2009;11(2):e9.

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## Supplementary information

1. Describe the alignment of the project with the HTMR Network strategy

This project aligns closely with several strategic objectives of the network. In particular: 1. Promoting high quality methodological research relevant to trials (this project will develop new methodology in an emerging sector), 4. Working with external stakeholders (this project will engage with the NHS and industry-based app developers), and 7. Strategic alignment and synergy with appropriate networks, (this project will be co-supervised by Farr Institute staff).

2. Does this project align with the work of a HTMR Working Group; if so, which?

This project aligns with the work of the Health Informatics working group.

3. Describe how this project aligns with the host Hub strategy

The host Hub's priorities are methods which have a direct impact on the design, conduct or primary analysis of our or other people's trials. This project aligns directly with the aim of improving the design of trials.

4. Detail of any Project specific training offered in the studentship

There is no planned specific training; this will depend on the successful candidate. Training is available locally in health informatics generally, and particularly in digital health issues, including the design of health apps. This is available, as needed, to provide a background in current app development methods and why they fit traditional trial approaches poorly.

5. Are there any prerequisite qualifications or experience for this studentship?

Candidates for an MRC-funded studentship must meet residence eligibility and hold qualifications in a relevant subject at the level of, or equivalent to, a good honours degree from a UK academic institution (see methodology website for more details- www.methodologyhubs.mrc.ac.uk).

For this project: there will be a large methodological component, thus we would like a quantitatively-skilled student.