# Healthy Mind: a study of a web and smartphone stress management tool

Submission date 18/07/2014	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
		[] Protocol	
Registration date	Overall study status	Statistical analysis plan	
03/09/2014	Completed	[X] Results	
<b>Last Edited</b> 04/01/2017	<b>Condition category</b> Mental and Behavioural Disorders	Individual participant data	

#### Plain English summary of protocol

Background and study aims

Healthy Mind is a smartphone application (app) and website made by health experts at the University of Southampton in the UK and Palo Alto University in the USA. It has lots of different tools that can help people deal with stress and encourage calmness. We want to find out how different people use Healthy Mind and whether they find it helpful. In this study, we will be looking at when users are most likely to notice and respond to messages sent from the smartphone app. The app uses machine learning algorithms (artificial intelligence) to decide when is the best time to send messages according to the time of day, physical activity or where the user is at that time. It is hoped that, by doing so, the message is at its most likely to reach the user and help them to manage stress. We also want to see how and when people use the app compared to the website.

#### Who can participate?

Anyone over the age of 18 years who has an Android smartphone/tablet or access to the Internet.

#### What does the study involve?

Participants can start using Healthy Mind by downloading the Android app to their smartphone /tablet or by visiting the Healthy Mind website. They are asked a few quick questions about themselves before using the service. Participants are then randomly allocated to one of three groups. Those in group 1 receive up to three messages a day depending on the data the app collects to decide when to send them. Those in group 2 receive one notification a day between 5pm and 8pm. Those in group 3 receive two messages a week between 5pm and 8pm. The message gives a suggestion on how to manage stress and invite the user to open the app for more information. All participants are sent an email around 2 weeks after they first used Healthy Mind to ask them what they think of it. If they answer this quick survey before 31st January, 2015, they will be entered into a prize draw to win one of four £100 cash prizes. Each participant can stop using Healthy Mind (or delete it from their phone) at any time.

What are the possible benefits and risks of participating?

Using the Healthy Mind tools can help to ease stress and help participants to feel more positive. The advice provided by Healthy Mind will not cause any harm. Healthy Mind should not be used as a treatment option by people diagnosed with anxiety of depression by a health professional.

Where is the study run from? University of Southampton (UK)

Who is funding the study? The EPSRC Engineering and Physical Sciences Research Council (UK)

When is study starting and how long is it expected to run for? September 2014 to February 2015

Who is the main contact? Dr Leanne Morrison healthymind@soton.ac.uk

**Study website** https://healthymindweb.lifeguidewebsites.org/player/play/healthymindweb

## **Contact information**

**Type(s)** Scientific

**Contact name** Prof Lucy Yardley

#### **Contact details** Academic Unit of Psychology Shackleton Building Highfield Campus University of Southampton Southampton United Kingdom SO17 1BJ

## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N/A

## Study information

#### Scientific Title

Optimal delivery of push notifications to promote usage of a smartphone-based stress management intervention: a randomised trial

#### **Study objectives**

This study will disseminate Healthy Mind a digital stress management intervention that is available as both a stand-alone Android application and a stand-alone website ('Healthy Paths').

The aim of this study is to compare usage of three different versions of the Android application that deliver push notifications at three different frequency schedules. The first version will apply machine learning algorithms to sensor data collected via participants smartphones to intelligently trigger notifications according to a participants current context (e.g. location, time of day, accelerometer etc.). The second version will automatically trigger one, daily notification, during a pre-defined time period. The third version will automatically trigger one notification every third day during a pre-defined time period.

It is hypothesised that greater intervention usage and faster response rates to the push notifications will be observed in the first (intelligent triggering) version, compared to the other two versions, since after an initial learning period notifications will only be delivered at inferred convenient moments. No hypotheses are made about differences in usage between the other two (non-intelligent) conditions since there is no clear evidence on the optimal frequency for triggering push notifications.

A secondary aim of the study is to observe and compare usage of the Healthy Mind Android application versus the Healthy Paths website.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

University of Southampton Ethics Committee and Research Governance office, 13/07/2014, ref. 10957

#### Study design

Randomised comparison of three intervention arms

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Quality of life

#### Participant information sheet

https://healthymindweb.lifeguidewebsites.org/player/play/healthymindweb? thiz=login\_regcomplete

#### Health condition(s) or problem(s) studied

Stress

#### Interventions

Healthy Mind is designed to help users manage stress and other difficult emotions. It provides a range of evidence-based tools taken from mindfulness therapy and cognitive behavioural therapy. It is available as a stand-alone Android application (downloadable from the Google Play Store) and a stand-alone website (accessed via a dedicated URL). The Healthy Mind tools are accessible on demand no restrictions will be placed on when or how often individuals are able to access the tools.

Users of the Android application will be randomised to one of three different versions of the app:

- 1. Intelligently triggered push notifications
- 2. Daily push notifications triggered within a pre-specified time period
- 3. Push notifications triggered every third day within a pre-specified time period

All participants will be asked to complete self-report questionnaires 2 weeks after registration.

#### Intervention Type

Other

Phase

Not Applicable

#### Primary outcome measure

Usage of Healthy Mind app:

- 1. Number/duration of log ins
- 2. Response rate and speed of response to push notifications
- 3. Number/duration of specific tool use

This will be measured continuously (i.e. each time the participant accesses the app).

#### Secondary outcome measures

- 1. Patient Enablement Instrument (Howie et al., 1998)
- 2. Positive Intervention Perceptions (Yardley et al., 2010)
- 3. Perceived ease of use (Venkatesh & Davis, 2000)
- 4. Preferences for app versus website
- 5. Usage of app versus website

All secondary outcomes will be measured 14 days post registration.

## **Overall study start date** 02/09/2014

Completion date 28/02/2015

## Eligibility

#### Key inclusion criteria

1. Adults aged 18 years or older

2. Able to access the internet and/or owner of Android smartphone/tablet

Note: Countries of recruitment we will primarily disseminate Healthy Mind via UK-based workplaces in collaboration with public health teams. However since our study will be administered online and several workplaces may have international sites we cannot rule out (and we will not restrict) participation from other geographic locations.

#### Participant type(s)

Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** 432

**Key exclusion criteria** Not provided at time of registration

Date of first enrolment 02/09/2014

Date of final enrolment 28/02/2015

## Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre University of Southampton** Southampton United Kingdom SO17 1BJ

### Sponsor information

**Organisation** University of Southampton (UK)

#### **Sponsor details**

c/o Dr Martina Prude Highfield Campus Research Governance Office Corporate Services Southampton England United Kingdom SO17 1BJ

**Sponsor type** University/education

Website http://www.southampton.ac.uk/

ROR https://ror.org/01ryk1543

## Funder(s)

**Funder type** Research council

#### **Funder Name**

Engineering and Physical Sciences Research Council (EPSRC) (UK) - Ubiquitous and Social Computing for Positive Behaviour Change (UBhave); Ref: EP/I032673/1

#### Alternative Name(s)

UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

**Funding Body Type** Government organisation

Funding Body Subtype National government

**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?
<u>Results article</u>	results	03/01/2017		Yes	No