

# Development and Evaluation of a PTSD Research App

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## AIM

Mobile mental health (mHealth) applications (apps) for PTSD patients have been shown to be effective in reducing PTSD symptoms and improving related outcomes such as psychosocial functioning and depression. mHealth apps can be easily integrated into daily life, do not signal mental illness, and can be used whenever the patient is in need of help (e.g. in triggering situations).

Currently, an increasing number of patients with PTSD symptoms are referred for treatment in Mental Health Services, Capital Region of Denmark. These patients are requesting tools which they can use at home as a supplement to treatment. Therefore, the development of mHealth apps for this population is a priority. At present, apps for PTSD are available for war veterans, but not for people with PTSD due to long-term effects of trauma such as childhood sexual abuse, rape, accidents or death threats. The aim of this study is therefore:

**To develop an app for the heterogeneous group of patients with PTSD and to test its efficacy as a supplement to outpatient psychiatric treatment.**

## APP DEVELOPMENT PHASES



The app was developed over the course of four phases in close cooperation with the app-development company BridgeIT.

**In the first phase, "Scoping"**, a requirement specification was developed concerning which functions the app should include to best support PTSD treatment across Mental Health Services, Capital Region of Denmark. These functions were selected based on a strategy framed by the second author's lengthy experience with treating PTSD patients in this setting, and included a thorough literature search, brainstorming sessions and consultations with experienced PTSD clinicians and researchers. At the same time, permission was sought from the Danish Data Protection Agency in the Capital Region of Denmark, and security procedures regarding both handling and storing data were agreed upon, described and approved by this agency. The research team described which data should be collected through the app (e.g. data regarding use of the app as well as the patients' self-reports of sleep quality and PTSD symptoms), and BridgeIT provided a technical solution that complied with the Danish Data Protection law to ensure that this was possible.

**In the second phase, "Design and Contents"**, the content of the app was decided by the study's first, second and fifth author. Design and graphics were developed by BridgeIT, music and sound were produced by professional musicians, the "help to fall asleep" function was recorded by professional actors, and soothing/calming pictures were provided by two amateur photographer and PTSD therapists. As an end to this phase, three PTSD patients participated in a workshop where they gave feedback on the provisional content and design of the app. It was the patients that provided inspiration for the name of the app.

**In the third phase, "Implementation"**, app functions were tested by the research team as well as five PTSD therapists who also provided feedback on design and content. Here, missing components and errors were corrected. Additionally, the web portal from which the first author can extract data from the app was tested and adjusted accordingly, such that it was in compliance with the rules set by the Danish Data Protection Agency in the Capital Region of Denmark regarding storing and handling of data.

**In the last phase, "Launch"**, the app was made available on the App Store and Google Play. To start with, the app can only be downloaded by patients that are part of the research project on evaluation of the app in a RCT feasibility study.

## PTSD HELP FUNCTIONS

The PTSD help app is designed to be used both as a stand-alone self-help tool and as a supplement to face-to-face PTSD treatment.

### Functions include:

- Psychoeducation about PTSD
- Information about options for PTSD treatment in the Danish public mental health sector
- Concrete techniques for relieving anxiety, such as breathing exercises, physical exercises and calming images
- Help towards better sleep through guided sleep exercises and advice for improving sleep habits and sleep environment
- Option for taking personal notes on symptoms and helpful strategies that can reduce these
- A crisis plan with personal contacts and contact information for psychiatric emergency services
- Tools for self-assessment and monitoring of PTSD symptoms (*PTSD Checklist for DSM-V*; Weathers et al., 2013) and sleep quality (*Sleep Condition Indicator*; Espie et al., 2014)



## RCT FEASIBILITY STUDY

PTSD help is a new mHealth app and as such needs to be tested clinically. Currently there is a lack of experience in the Danish psychiatric system with regards to RCTs of mHealth apps. Because of this, a feasibility study is necessary to ascertain the possibility of conducting a large-scale effect RCT of PTSD help.

### The primary aims of the RCT feasibility study are:

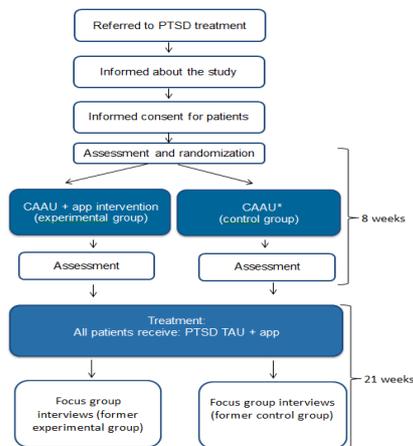
1. To determine a suitable sample size for a large-scale RCT efficacy study, and to investigate whether it is possible to recruit an adequate number of compliant out-patients from the Mental Health Services, Capital Region of Denmark.
2. To collect feedback from patients regarding the usefulness of the app as a self-help tool and as a supplement to therapy, for the purpose of making necessary adjustments to the app in preparation for a large scale RCT.

Thus, the study is divided into two sub-projects:

**Sub-project 1** uses a randomized controlled design. Data will be collected before treatment begins, and the primary outcome measures will be randomization data and user behaviour data collected through the app.

**Sub-project 2** uses a naturalistic design and runs from the beginning to the end of psychotherapeutic treatment. The primary outcome is qualitative data about the user's experiences with the app, collected through focus group interviews at the end of treatment.

## STUDY FLOWCHART



\*CAAU (Clinical Assessment As Usual)



BRIDGEIT

IT/App-developer

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OFFERFONDEN

"PTSD help" is developed by Mental Health Services, Capital Region of Denmark, Research Unit and Competence Centre for Psychotherapy, Stolpegård Psychotherapy Centre

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