

August 2020



TACKLING CHRONIC DEPRESSION

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TACK activities between April and August were focused on ensuring research continuity during the COVID-19 pandemic. Following the permission from the TACK study Sponsor the researchers have moved to conducting follow-up interviews over the phone, while some clinicians kept delivering the DIALOG+ intervention remotely. We are currently preparing for the restart of participant recruitment.

April – August 2020 Update

Following the decision by the TACK study Sponsor (NOCLOR) on 16th March 2020 to suspend all research activities with immediate effect due to the COVID-19 pandemic, we obtained permission for the TACK researchers to conduct follow up assessments at 3, 6, and 12 months over the phone. A specific guidance on remote interviewing was provided to the researchers in the existing sites in Gloucester, Oxford and Sheffield, who have since successfully transitioned to remote data collection.

We have also obtained permission for the TACK clinicians to carry on conducting DIALOG+ intervention over the phone and produced the guidelines for remote delivery. However, some TACK clinicians have been temporarily redeployed to other duties due the pandemic so not all of them were able to continue delivering the intervention in this period.

Qualitative interviewing for the feasibility study was finalised with 7 service users and 6 clinicians interviewed in total.

The recruitment has been postponed in the newly launched sites Essex and Devon, while the study launch in the new sites of NELFT, SLAM, and Somerset has been delayed.

TACK study restart

Following the publication of the Guidelines for the restart of NIHR research studies, Phil carried out extensive consultations with the all the TACK sites about the amendments to procedures and COVID-19 security measures required. The relevant information was subsequently provided to the Sponsor and we are now awaiting their approval for the restart of the recruitment.

In the light of the ongoing pandemic and the need to follow social distancing policies we have amended the study protocol so that all activities can be completed remotely. This includes the ability to consent remotely, as well as face to face. The assessments will mostly be carried out remotely but with the face-to-face option if required and safe to do so.

We have been also developing remote clinician training for the DIALOG+ intervention and active control in order to reduce the need to travel. The researchers have been contacting interested clinicians in the TACK sites about the restart and possible future involvement.

Following the approval, the study will be gradually re-launched to test the amended procedures and start recruiting service users and clinicians.

LEAP meeting

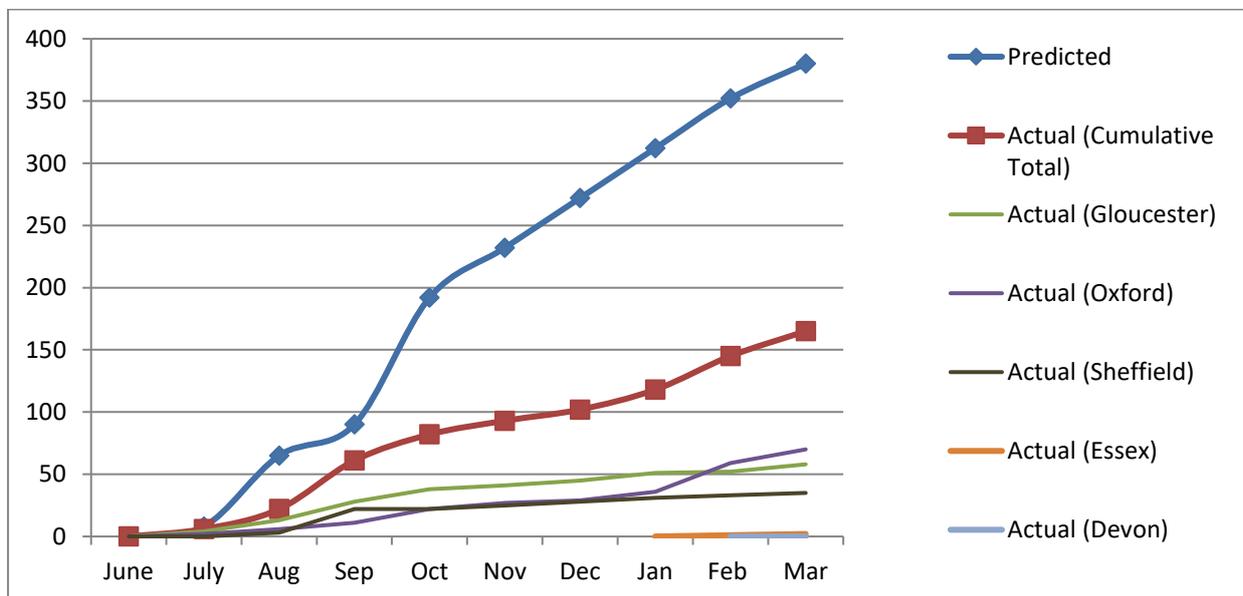
The 8th TACK LEAP meeting was held remotely on 28th May 2020. Phil provided the update on the TACK study and the COVID-19 research continuity plan. The issues related to remote assessments have been discussed. Following the meeting, the LEAP expert members provided the comments on the guidelines for remote interviewing which were incorporated in the training. The new LEAP meeting will be organised for the 2nd half of September.

New Researchers

We have welcomed several new researchers on the TACK since April: Kate Manhattan (Oxford) Esther Webster (Gloucester), Lauren Jerome (London), Matthew Mills and Jonathan Woods (Sheffield). This was obviously a strange time to start a new role but they have all done brilliantly with getting to grips with project.

Recruitment and Data Collection Update

The number of participants who have consented into the study as of 16.Mar.2020 (when the study was temporarily suspended) are 165 service users and 99 clinicians. The original target number for this date was 380 service users and 104 clinicians. The lower than predicted recruitment was partly due to a delay in launching new sites. In January the TACK Steering Committee approved an internal 3 month extension to the recruitment period, until 30.Sep.2020. In February the TACK teams in the existing sites managed to improve the recruitment rates and hit their targets in February and we were also ready to launch the study in several new sites the following month. Unfortunately, all recruitment was stopped on 16th March 2020 due to the pandemic and we now expect to recruit until the end of December 2020. In terms of data collection, 142 baseline assessments, 86 3-month assessments, and 52 6-months assessments have been carried out. 12 month follow ups will begin in September.



Predicted vs actual recruitment of service users into the main trial as of 16.March.2020