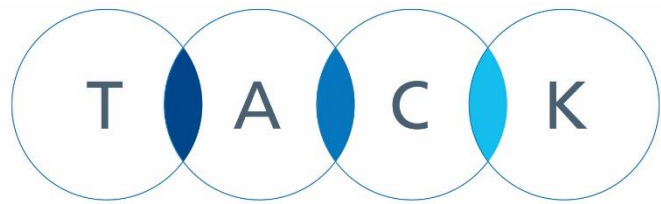


November 2020



TACKLING CHRONIC DEPRESSION

*TACK recruitment restarted in early September following the amendments which allowed all the recruitment and data collection procedures to take place remotely. The recruitment period has been extended until 31<sup>st</sup> March 2021. The WP4 database went live on 29<sup>th</sup> September 2020. All the data collected by 9<sup>th</sup> October 2020 was entered into the database and analysed for the independent Data Monitoring meeting.*

### The TACK Study Restart

The TACK study received permission to restart on the 28<sup>th</sup> Aug 2020. Recruitment was immediately initiated in four sites: Oxford, Gloucester, Sheffield and Devon. The restart in Essex was delayed until December 2020 due to a pandemic related delay in returning to research activities. North East London NHS Trust Foundation (NELFT) was added as a new site in November, while Somerset and South London & Maudsley (SLAM) will open in December. The recruitment period for the main trial has been extended until 31<sup>st</sup> March 2021.

In the light of the ongoing pandemic we have received permission to consent participants and conduct assessments remotely (over the phone or virtual platforms). Participant information sheets and consent forms have been amended accordingly. Active Control Group procedures have been changed so that the participants now complete the DIALOG Scale on paper at home after the online sessions with their clinicians. This was done in order to avoid contamination that may occur if the clinicians write down their ratings. The DIALOG Scale forms will be supplied and collected by the TACK researchers. We have also developed additional online resources to support remote DIALOG+ training of the TACK clinicians.

### Data Monitoring & Ethics Committee (DMEC) meeting

The 3<sup>rd</sup> DMEC meeting was held on the 13<sup>th</sup> November 2020. The recruitment figures and the summaries of data collected by 9<sup>th</sup> October 2020 were presented to the members. DMEC members expressed their satisfaction with the study progress, given the challenging circumstances.

The average age of 120 participants from both the intervention and the control group was 46 years, with 68% being female and 32% male. The length of treatment was 14 years on average. The sample was predominantly White, which we hope to address in the coming months by focusing on recruitment in more diverse London areas. The participants reported severe depressive symptoms (MADRS: 30.9), and a low subjective quality of life (MANSA: 3.2). They were deemed severely ill by their clinicians with the average CGI score of 4.3. At 6 months, the participants' subjective quality of life was slightly higher (MANSA: 4.5) and their depressive symptoms lower (MADRS: 24.3). At 12 months, there was little change on most measures apart from decreasing SQOL (MANSA: 3.2), but this is based on data from a very small number of participants. Both the intervention and the control group participants have similar characteristics indicating a successful randomisation process.

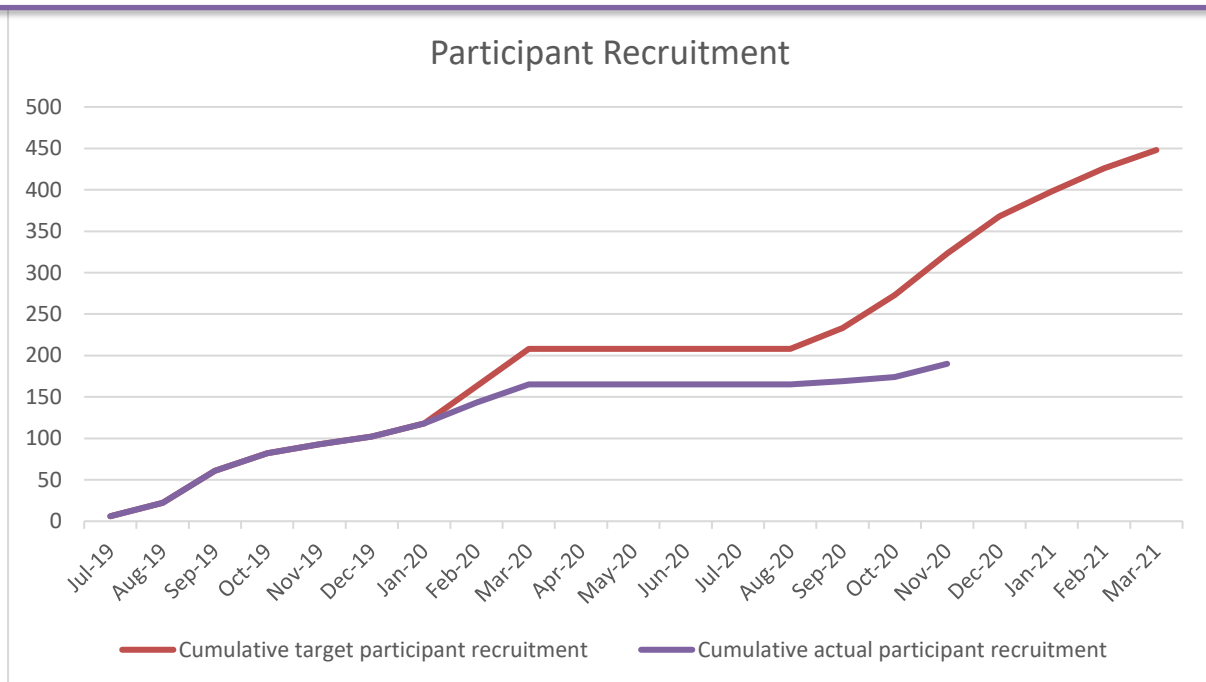
## LEAP meeting

The 9<sup>th</sup> TACK LEAP meeting was held remotely on 25<sup>th</sup> September 2020. The LEAP members were updated on the TACK study restart and the current state of the recruitment. They provided suggestions for a draft of the Service User topic guide for the planned qualitative study about experiences of receiving DIALOG+ intervention (WP5). Several members agreed to take part in filming the DIALOG+ training videos. They will use their lived experience to produce more realistic role-plays. The LEAP members suggested and helped to develop a list of national and local resources for mental health support that will be provided to distressed participants who are not treated in secondary care at the point of being contacted by researchers for follow ups.

### Recruitment and Data Collection Update

The number of participants who have consented into the study as of 30.Nov.2020 are 190 service users and 119 clinicians. The original target number for this date was 323 service users and 112 clinicians. In terms of data collection, 187 assessments were conducted at baseline, 78 at 3-months, 71 at 6-months and 41 at 12 months. We have received permission to increase the upper age limit in the inclusion criteria to 100 so we can recruit more participants from Older Adult Services in some of the sites.

TACK Programme Steering Committee approved the internal extension of the recruitment period till the 31st March 2021. A potential further extension to the duration of the Programme has also been discussed with the PSC and the Funder. It was agreed not to submit an official request until Spring/Summer when we will have a better idea of realistic recruitment rates and the length of the extension required.



### Predicted vs actual recruitment of service users into the main trial as of 30.Nov.2020