June 2021



Following approval from the Programme Steering Committee and the Sponsor, the TACK trial recruitment period was extended by 6 months until the 30th September 2021. The TACK researchers have been working hard to keep recruitment of participants going across all existing sites. Lancashire and South Cumbria NHS Foundation Trust have been added as a new site and will start recruiting soon. We have started conducting qualitative interviews about the experience of delivering and receiving the DIALOG+ intervention with patient participants. A request for a 12 month costed extension to the Programme Grant will be submitted by the end of June.

TACK RCT progress

The TACK study researchers in the 7 active trial sites have been making significant effort to recruit new participants into the study and to keep the follow-ups going. Lancashire & South Cumbria NHS Foundation Trust have been added as a new site, with both the site initiation visit completed and the local researchers trained. One CMHT will be participating as part of a pilot of DIALOG+implementation for the whole Trust.

As a part of the Process Evaluation (WP5), we have started conducting qualitative interviews with the service users and clinicians from the intervention group. We are using a purposive sampling for selecting participants to ensure that a variety of experiences is captured in the data collected. So far, we have interviewed 5 service users and 5 clinicians. The participants are approached as they complete the intervention delivery after 12 months.

The activities of Training Package (WP6) have also been initiated. We will recruit 20-30 clinicians across different services such as IAPT, Inpatient wards, Occupational therapy etc. and adapt the standardised training package. We will assess the feasibility of training and any additional training needs from these different settings.

Project Meetings Update

The 10th Programme Steering Committee (PSC) meeting was held on the 18th June 2021. The 8th and 9th Programme Management Group (PMG) meetings were held on 21st April and 21st June 2021. PSC members were supportive of the TACK RCT and the progress made so far despite the challenging circumstances. They believe that the TACK is delivering clinically valuable research and have encouraged submitting a request for a 12 month extension. The TACK co-applicants from the PMG were equally complimentary about the progress and supportive of the extension request.

Lived Experience Advisory Panel (LEAP) activities

The 11th TACK LEAP meeting was held remotely on 23th April 2021. In addition to the TACK study update, Renata Peppl from QMUL presented the PIECEs project, a study looking at the application of DIALOG+ for people with psychosis in India & Pakistan. The LEAP members have agreed to advise the PIECEs researchers on initiation of PPI panels and a first meeting is currently being organised. A meeting with the LEAP members from India and Pakistan to share experiences is also planned. Four LEAP members have expressed interest to be included in the TACK qualitative analysis and will be trained on the 25th June.





The analysis of data collected within the TACK feasibility trial has recently been completed. We have received some encouraging early results, with quality-of-life scores being higher and depressive symptoms lower in the DIALOG+ intervention group at 6 months. This provides an indication that the DIALOG+ may be an effective treatment for chronic depression. However, we need to bear in mind that the feasibility trial was not designed to detect differences but to develop procedures and test the instruments before the main RCT. The results will be described in a mixed methods journal article focusing on the intra-group differences and confidence intervals. These will be combined with the qualitative findings on the experiences of delivering and receiving DIALOG+. The qualitative data will be re-analysed with the help of the LEAP members who will receive the relevant training.

Recruitment and Data Collection Update

323 service users and 172 clinicians have been consented into the study as of 16th June 2021. 62 clinicians have withdrawn after consent mainly because of COVID, but also due to them leaving their post or not being able to recruit sufficient number of participants for their cluster. Due to this large drop-out we will need to carry on recruiting clinicians beyond the original target of 112. 296 participants have completed baseline assessments. A total of 70 clusters have been randomised so far (70 clinicians and 233 service users). The average cluster size currently stands at 3.33.

We still need to recruit around 150 more service users to reach the original target (448). Opening in the new trial sites will help us towards this target.

A 6 month extension to the TACK recruitment period was approved by the funder (NIHR) in March 2021, with the new recruitment end date being 30th September 2021. Following PSC approval and the consultation with all the sites, we will now apply for a 12 month costed extension to the overall Programme Grant, with the new end date of 31st March 2023.



