



## Feasibility Study

The feasibility study is drawing to an end, as the final few participants complete their therapy. Our site clinical teams and researchers have stepped up to the challenges of running the study and delivering therapy during this difficult time, and we are extremely grateful to everyone involved.

In terms of targets, the feasibility study has gone well. We recruited our target of 30 participants. The majority of participants have attended at least one therapy session, meeting our acceptance criteria. We have also been pleasantly surprised by the number of participants who have attended all 12 therapy sessions. Response rates to the monthly SMS follow-ups have been consistently positive and we are now in the midst of sending out the 6 month follow up questionnaires. Work has also begun on rating the fidelity of the therapy delivered. Again, the initial impression of therapy fidelity, from the supervising therapists, is positive and we believe we will meet this target too.



Of course there have been some bumps along the road. We have learnt from these and made some changes to the protocol for the RCT to address these issues. We have added another step in our screening process to reduce the number of early withdrawals. For the RCT, sites will have local researchers, who will be Trust employees with access to patient records. This will hopefully improve

lines of communication between the study team and site clinicians, and cut the wait time from initial screening to first therapy session.

Overall, we are really pleased with how well the feasibility study has gone. All our thanks go out to everyone involved in pulling it together, to the clinical teams who delivered the therapy and to all the participants who have taken part.

## RCT Planning and progress

Work is well underway for the randomised controlled trial (RCT), which we hope to open to recruitment in October 2021. We will be recruiting 630 participants across 12 sites, with 6 opening in the autumn and a further 6 to be opened early in 2022.

Currently we are eagerly awaiting the outcome of the regulatory approvals from the Research Ethics Committee and the Health Research Authority. There is also much activity behind the scenes preparing the training and supervision for all the therapists at the sites.

## Publications

We have two papers from the systematic review in the submission process, as well as a paper from the COVID study carried out last summer, which has been submitted for review. Fingers crossed this will result in some publication news very soon!

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## Recruiting for the Feasibility Study – A reflection

The COVID pandemic meant we had to make many changes to the way we work, and this has included how we approached recruitment into the feasibility study. The initial plan had been for the researchers to complete the recruitment baseline and consenting in person but this of course was no longer possible.

We moved to completing the baseline and consenting calls over the phone. Ahead of the feasibility study opening, the researchers conducted a small study around how COVID and restrictions have affected people who self-harm. The interviews for this study were carried out over the phone as well. The two researchers involved received some excellent training and advice from the team at Self-Injury Support, but even so they were surprised to find that having these conversations on the phone, in your own home, was much more difficult than in the office. The team quickly built in processes to protect our researchers mental health, with debrief calls and time built in to decompress, and we took this learning forward into the recruitment for the feasibility study as well.

As well as keeping our researchers safe, we also had to make sure we were still able to keep the potential participants we spoke to safe as well. During face-to-face visits, researchers would have been on hand to help manage a potential participant's distress, to sit with them as they work through it, or until someone else, such as a friend, arrived to support them. It was much more difficult for the researchers to provide the same level of support over the phone. As such, we set up a system to ensure there was always a clinician available for the participant to speak to if there were any concerns during baseline calls.

These baseline calls also highlighted just how different any one individual's experiences and needs can be, and how difficult it is to assess a potential participant's eligibility for inclusion in the trial. In research we often talk about the population group we are working with as if they are one homogenous group, but quite

clearly they are all individuals as well. Each participant we spoke to raised new questions and these were important for informing our planning for the RCT. We have adapted and expanded the details of our exclusion criteria for the RCT in response to this, but we are fully aware that we will never be able to cover all eventualities. No one person will have the same story as another, and this will always pose new questions to consider.

Recruitment to the feasibility study has also reinforced the issue of unequal representation of diverse groups in mental health research. This can reinforce the inequalities in mental health care which impact certain groups, such as people from ethnically diverse communities, and lower income households. In order to improve services for all, we need to work on including people from diverse ethnic groups, all genders, disabled people and the LGBT+ communities. The FReSH START team are striving to gain representation from these different groups in our PPI network so that we can work together to increase the representativeness of our research in the future, and hopefully in the upcoming RCT.

Looking back on the conversations our researchers had during recruitment, one key message that kept coming through was just how much a self-harm focused therapy was needed. Many of the participants spoke about how there was nothing available for them in mental health services, or how what was available was not appropriate. We really hope that FReSH START can help bring this about, to improve support and services in the NHS for people who self-harm.

### Lived Experience Group



We are currently recruiting for our lived experience group, to support FReSH START and another self-harm research project call SafePIT. We have attached the flyer for this network and would appreciate it if you could circulate this amongst your networks as appropriate.