A series of five examples of public involvement in research developed by the NIHR Evaluation, Trials and Studies Coordinating Centre.

Example 1: Preventing depressive relapse in NHS Practice through mindfulness-based cognitive therapy (MBCT)

About the research

Lead researcher: Professor Willem Kuyken, College of Life and Environmental Sciences, University of Exeter.

Funder: National Institute for Health Research Health Technology Assessment (HTA) Programme.

Project aim: To assess whether MBCT can help people with a history of recurring depression stay well, as an alternative to staying on their anti-depressant medication over a two year period.

Type of research: Randomised controlled clinical trial.

Duration: Four years – started January 2010.

Who we spoke to

We interviewed the lead researcher Willem Kuyken. His comments are written in blue text below.

About the involvement

How patients have been involved in the trial

People with experience of depression have been involved at all stages of the research, from developing the research question, through to running the trial and collecting data. They will also be involved in planning and running workshops to disseminate the results. There are service user members on the Trial Steering Group with responsibilities for governance and oversight, and on the Trial Management Group with responsibilities for managing the trial. The impact of the involvement has therefore been extensive, with the service user perspective influencing every aspect of the project. In this example, we focus on the involvement of people with experience of depression in training members of the research team.

Service user involvement in training researchers to obtain consent

Members of the research team were trained by a service user to improve the process of obtaining consent from potential trial participants. The training involved role-play and helped shape the team's policy and practice. The trainer encouraged the

researchers to pay attention to all parts of the process, not just the written information, but also their verbal communication and body language.

> "As a researcher you have lots of assumptions about what people may or may not know, or may or may not be concerned about – the training made that all really explicit. The service user trainer knew the study well and was able to highlight the parts of the patient information sheet that we needed to talk through with people every time. Academics can assume that providing written material is a compelling way to communicate – but that's not true for everyone." **Willem**

The service user trainer also introduced an extra step in the consent process, to ensure that participants had really understood what they were signing up to. This involved asking potential participants to describe in their own words what they understood would happen to them after they had entered the trial.

> "As a result we felt that people were properly informed and engaged in the consent process. I don't have the data to prove this, but we were also likely to have people who are very committed to the trial. We have super retention rates, over 86%, which is unprecedented, and I guess having really good consenting procedures is a significant part of this. " **Willem**

Service user involvement in risk training for the researchers

At an early stage in the research, the team developed a protocol to manage the risks around participants being suicidal or reporting suicidal thoughts. The protocol was co-developed with a service user who also provided training on putting the protocol into practice. This involved role-play and giving the researchers feedback on their performance.

> "Many of our researchers are young psychology graduates, who have some anxiety about talking to people who have had suicidal thoughts. They fear that opening up this topic will open up a Pandora's Box or put the idea of suicide into someone's mind. The service user trainer explained that the opposite is true – that the researchers don't need to be frightened to ask the question and that people with depression may find it a relief to be able to talk about it. To hear that from a person with lived experience, rather than from me or the trial manager, had more potency and authenticity. It was the same doing the role-plays with the service user trainer – it made it more real for our researchers." **Willem**

The training also emphasised that the protocol was as much about protecting the researchers as protecting the participants, and was therefore drafted in a way that provided more structure and support to the researchers.

Lessons learnt

> "The best clinical research is based on collaboration. The idea of one academic coming up with the idea and leading on a project on this scale just doesn't work. It requires a team of people bringing different expertise, so that the user voice weaves through every aspect. As I was even thinking about applying for a grant, I was listening to my patients and asking 'Is this an interesting question, would it be feasible to do this?' Building in a patient and public involvement (PPI)

perspective is one of the values underpinning this project. It's the way I work and think.

When you work with service users who have depression they may become depressed, sometimes for a period of months. So when you sign someone up to be part of the team, you need to build in the fact that they may become ill while you're working together, and ensure there is someone else who can help out at those times. You need to make it clear that you will be available when the person is ready to come back to work – but that you're not their therapist. All of those boundaries need to be clear and established from the beginning. " **Willem**

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References:

Kuyken, W., Byford, S., Byng, R., Dalgleish, T., Lewis, G., Taylor, R., Watkins, E.R., Hayes, R., Lanham, P., Kessler, D., Morant, N. and Evans, A. (2010). Study protocol for a randomized controlled trial comparing mindfulness-based cognitive therapy with maintenance anti-depressant treatment in the prevention of depressive relapse/recurrence: the PREVENT trial. BMC Trials, 11, 99. doi:10.1186/1745-6215-11-99