CHIEF SCIENTIST OFFICE

CODE: HIPS/18/60

RESEARCH PROJECT BRIEFING

Supporting treatment decision-making in psychosis: The DEC:IDES trial

AIMS

- To begin developing ways to support people with psychosis (i.e., schizophrenia-spectrum disorders) to make their own decisions about their mental health treatment.
- To find out if they will take part in and complete a new type of study, called an 'Umbrella trial', which tests several ways of supporting treatment decision-making at the same time.

KEY FINDINGS

- Our goals were (i) to recruit 20 people to each of three randomised controlled trials (60 people in total) and (ii) conduct post-treatment assessments with at least 75% of them (45 out of 60). One trial tested the effect of improving 'self-stigma' on treatment decision-making ability. Another tested the effect of improving self-esteem and another tested the effect of encouraging people not to 'jump to conclusions' (JTC) when making decisions.
- We recruited 57 people. They took part in the study 60 times (3 people took part in two of the trials). We conducted 50 of the 60 (83%) possible post-treatment assessments.
- 25 people took part in the self-stigma trial and 23 took part in the JTC trial. Only 12 people took part in the self-esteem trial. Low self-esteem was much less common in this group of patients than we predicted.
- One person experienced a serious adverse event which was likely caused by our research procedures. Asking this person questions about their mental health during their initial assessment appeared to cause their symptoms to worsen, which caused them to leave the study early. This happened before they received any of our clinical procedures (i.e., therapy or further clinical assessment).

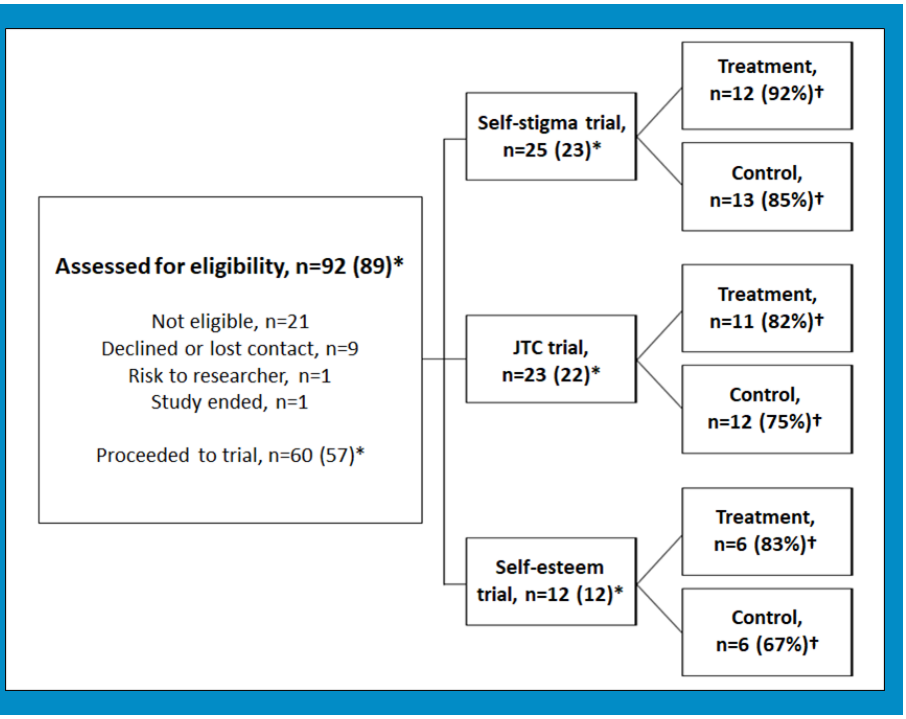
WHAT DID THE STUDY INVOLVE?

- Allocation of participants to one of three clinical trials, all running at the same time.
- Provision of 6 hours of specialised therapy (over 8 weeks) for their presenting problem, or a control condition (6 hours of assessment of factors affecting their decision-making)
- Assessment of participants before and after they took part. Some were also assessed again, 16 weeks later. Some were also asked about their experiences of participation.
- Inclusion of service users and clinicians in our Trial Steering Committee.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

- Recruitment opened just 4 weeks before the COVID-19 pandemic led to the first UK-wide lockdown. We extended the overall study from 19 months to 34 months to mitigate the effects of this, service and ward closures, and other pandemic-related challenges.
- Despite the pandemic, we succeeded in conducting 60 randomisations, and in gathering post-treatment data from 83% of participants. The study was acceptable and safe for most people. These findings suggest it is feasible to conduct clinical trials of interventions to support treatment decision-making capacity in psychosis. They also suggest that Umbrella trials are feasible to conduct in this group, and in mental health generally.
- We over-recruited for our self-stigma and JTC trials, but recruited only 12 people for our self-esteem trial. This is because far fewer people (32%) had low self-esteem than we predicted (80%). Our approach to testing low self-esteem interventions for this group may need to be modified before we can be confident it is feasible on a larger scale.

This figure summarises the flow of participants through the study. The numbers marked with an asterisk indicate the number of unique participants (3 participants took part in the study twice). The percentage marked with a '†' refer to the proportion of people in each arm who attended their post-treatment assessment.



WHAT IMPACT COULD THE FINDINGS HAVE?

- **Patients:** The feasibility of DEC:IDES means it will now be possible to do a larger-scale version to see if these and other therapies can help people regain their ability to make decisions about treatment
- **Policy:** Umbrella trials are feasible to run in a mental health setting. This could accelerate the development of treatments for other mental health problems.
- **Practice:** A proportion of people with psychosis who are unable to make decisions about treatment are willing to collaborate with professionals to help them regain this ability.

HOW WILL THE OUTCOMES BE DISSEMINATED?

- Online dissemination events for (1) practitioners, (2) patients and public, (3) current and potential academic partners
- We will publish all our peer-reviewed results on our trial website, and send consenting participants a link to this. Easy-read summaries will be provided. If resources allow it, we will also upload audio and or video versions of the easy-read summaries.
- Publication in a scientific journal and at academic conferences

CONCLUSION

- It is feasible to conduct clinical trials of interventions to support treatment decision-making capacity in psychosis.
- It is feasible to conduct Umbrella trials in this group, and in mental health generally
- A larger-scale version of DEC:IDES is warranted

RESEARCH TEAM & CONTACT

Professor Paul Hutton (Chief Investigator) & Dr Amanda Woodrow (Trial Manager), on behalf of the DEC:IDES research group

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Additional Information

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