

The Impact Study: A Cluster-randomised Clinical and Health Economic Feasibility Study of a Theory-based Manualised Intervention to Support People With Tuberculosis Disease During Treatment

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Rationale: Taken as prescribed, treatment for tuberculosis (TB) cures >90% of people with drug-sensitive disease. Approaches to minimise non-adherence often do not address wider psychosocial and structural factors. We developed a theory-based manualised intervention including enhanced structured needs assessment, educational videos, and an interactive patient booklet, to support patients with psychosocial and structural barriers to adherence during their anti-TB treatment (ATT). We report the intervention's acceptability to people with TB and preliminary evidence of its influence on perceptions and behaviour, compared to a standard needs assessment. We also evaluated the feasibility of capturing resource use (including that arising from the needs assessments) and health-related quality of life (HRQoL) data to inform cost-effectiveness analysis planning for a definitive trial. Methods: Adults starting ATT were recruited from four London, UK, TB centres (two randomised to intervention, two to control). We assessed acceptability through process evaluation, patient perceptions using the Beliefs about Medicines Questionnaire, resource use with a modified Client Service Receipt Inventory and patient case notes, and HRQoL with EQ-5D-5L. Electronic monitoring boxes recorded medication use (proportion of doses taken over 168 days from initiation). Results: 79 people with TB were recruited (36 intervention, 43 control). Study arms were balanced for ethnicity and gender. Age ranged from 18-81 years (largest group 28-38 years). The intervention arm detected more individuals thought to be at risk of non-adherence (21/36 vs 4/43, $p<0.001$). Participants responded positively to all intervention elements, with mean helpfulness ratings (min0-max100) of 86 (patient booklet), 82 (needs assessment), 77 (medication diary/plan) and 72 (videos). The intervention resulted in increased perceptions of treatment necessity compared to controls between 2 weeks and 3 months of ATT (adjusted mean difference = 0.49, CI 0.11 - 0.97) ($p=0.05$). The cluster-level mean proportion of doses taken was similar in the standard care and intervention arms (0.88 and 0.81 respectively, mean difference -0.07, CI -0.41-0.27) ($p=0.23$). Adjusted estimates were also similar. Completion rates of CSRI and EQ-5D-5L ranged between 71-99% across timepoints. Conclusions: The IMPACT TB study indicates that collecting patient-reported and record-based resource use and HRQoL data is feasible; and that the intervention is acceptable to patients and improves identification of those potentially at risk of non-adherence to ATT. It may change people's perceptions regarding the necessity of their treatment. The high level of measured adherence in both arms could reflect the test population and

requires further exploration in a larger, definitive study.

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