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Autopsy of a failed trial part 2: outcomes, challenges, and lessons learnt from the DAISIES trial

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Publication

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Abstract

Objective

The relative merits of inpatient or day-treatment for adults with anorexia nervosa (AN) are unknown. The DAISIES trial aimed to establish the non-inferiority of a stepped-care day patient treatment (DPT) approach versus inpatient treatment as usual (IP-TAU) for improving body mass index (BMI) at 12 months in adults with AN. The trial was terminated due to poor recruitment. This paper presents outcomes and investigates the reasons behind the trial's failure.

Method

Fifteen patients with AN (of 53 approached) participated and were followed-up to 6 or 12 months. Summary statistics were calculated due to low sample size, and qualitative data concerning treatment experiences were analysed using thematic analysis.

Results

At baseline, participants in both trial arms rated stepped-care DPT as more acceptable. At 12 months, participants' BMIs had increased in both trial arms. Qualitative analysis highlighted valued and challenging aspects of care across settings. Only 6/12 sites opened for recruitment. Among patients approached, the most common reason for declining participation was their treatment preference (n = 12/38).

Conclusions

No conclusions can be drawn concerning the effectiveness of IP-TAU and stepped-care DPT, but the latter was perceived more positively. Patient-related, service-related and systemic factors (COVID-19) contributed to the trial's failure. Lessons learnt can inform future studies.

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