Phase II cluster randomized waitlist controlled trial of a multicomponent non-pharmacological intervention to prevent delirium for inpatients with advanced cancer (ACTRN12617001070325P)

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BACKGROUND

Delirium is prevalent, debilitating and distressing for people with advanced cancer in hospital. ^{1,2} Delirium can be prevented in one in three older patients by multicomponent interventions address essential human needs for physical and cognitive activity, sleep, hydration, vision and hearing. ^{3,4} The intervention required testing in an advanced cancer inpatient population.

OBJECTIVE

To determine if a multicomponent non-pharmacological delirium prevention intervention was feasible, acceptable and deliverable with high adherence and fidelity in people with advanced cancer in hospital, prior to a phase III trial

METHODS

Design: Phase II cluster randomized controlled trial of a multicomponent non-pharmacological delirium prevention intervention
Setting and participants: Four Australian palliative care units were randomized to intervention or control + waitlist intervention (figure 1). Data were collected for 65 adult patients with advanced cancer.
Control: Delirium screening using the Nursing Delirium Screening Scale (NuDESC) ⁵ and diagnostic assessment using the American Psychological Association Diagnostic and Statistical Manual 5th edition (DSM-5), ⁶ operationalized by the Delirium Rating Scale-Revised-98 (DRS-R-98). ⁷
Intervention: Delirium screening, diagnostic assessment and prevention strategies targeting eating and drinking, sleep, exercise, reorientation, vision and hearing, and enabling family (figure 2)

Figure 1: Study design

- Implementation:**
- Guided by Michie's Behaviour Change Wheel
 - Two-months site training and engagement
 - Interdisciplinary working groups
 - Intervention delivery tailored by team
 - Strategies tailored to patient need

Figure 2: Intervention domains

Primary endpoint: At least 60% of patients having at least four completed domains for at least five of the first seven days of admission

Secondary outcomes: Rates of interdisciplinary involvement; rates of delirium measure completion, delirium incidence and severity; adverse events; perspectives of patients, family, staff and volunteers about feasibility and acceptability of the intervention

Figure 3: CONSORT diagram

Figure 4: Adherence ≥ 4 domains ≥ 5 days

Figure 5: Adherence by domain

Every strategy was delivered more often at waitlist intervention sites.

- Secondary outcomes**
- Nurses completed 98% delirium screens
 - Physicians completed 77% diagnostic assessments
 - No difference in weekday and weekend completion of measures or intervention delivery rates
 - Nurses (67%), physicians (16%), allied health (8.4%), family (7%), patients (1%) and volunteers (0.5%) delivered the intervention
 - Delirium incidence (DSM-5) was 32% at control sites compared to 20% at intervention and waitlist intervention sites ($p=0.5$)
 - Mean (SD) delirium severity (DRS-R-98) at diagnosis was 16.8 ± 12.0 for patients at control sites compared with 18.4 ± 8.2 at intervention sites ($p=0.6$) and 18.7 ± 7.8 at waitlist intervention sites ($p=0.5$)
 - The intervention caused no adverse events
 - Qualitative data informed in-trial processes, adherence results and refinement of the intervention for a phase III (effectiveness) trial

CONCLUSIONS

Despite lower than anticipated adherence to the intervention, secondary outcomes indicated that a phase III trial is feasible with modifications. These modifications include: a simplified intervention, assignment of roles according to strategy, more precise dose measurement and processes to increase the involvement of family caregivers and volunteers in delivery of the intervention. We will also tailor outcomes to patients who are highly at risk of delirium and dying during hospital admission.

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