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Supporting Information

Supplementary materials

This appendix was part of the submitted manuscript and has been peer reviewed.
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Appendix to: Haines TP, Palmer AJ, Tierney P, et al. A new model of care and in-house general practitioners for residential aged care facilities: a stepped wedge, cluster randomised trial. *Med J Aust* 2020; doi: 10.5694/mja2.50565.

1. Contamination-adjusted intention-to-treat analysis

A contamination-adjusted intention-to-treat approach has been recommended for randomised controlled trials in which all patients are analysed as they were randomised and then the result adjusted for treatment contamination by using an instrumental variable that does not have an effect on the outcome other than that mediated via the endogenous variable of interest (in this case, the process measure of whether the GP was present). It is common when using this approach in randomised trials to use the random allocation variable as the instrument variable.[1] The instrument variable must satisfy two assumptions; i) that it is relevant (correlated with the endogenous variable of interest), and ii) that it is exogenous (not correlated with the error term from the model).[2] In this trial, the effect of randomisation may have had an effect on one or more outcome measures that was mediated through the second part of our intervention; the change to model of care. This would violate the assumption of exogeneity. We therefore examined this assumption using an approach described previously.[3] Here we repeated our secondary analyses with replacement of the variable coding for intervention/control period with the process measure of whether a GP was employed at the facility for more than half of the 9-week block. We captured the residuals (errors) from this model and examined their correlation with our intended instrument variable (the variable coding for intervention/control period) using an auxiliary ordinary least squares regression. We only proceeded with this analysis if the *P*-value of this association was greater than 0.80, indicating over 80% probability that the instrument and the errors were not associated, as instrumental variable analyses can produce biased estimates if instrument variables are only semi-exogenous.[4] In cases where we did proceed, we examined the assumption of relevance of the instrument using Anderson's underidentification test,[5] and the strength of the instrument using the Cragg–Donald Wald *F* statistic.[6] This analysis was implemented using the fixed effects version of the *xtivreg2* command in Stata MP 14.0. Outcomes that were count variables were given a log normal (x+1) transformation and had the number of resident occupied bed days included as an independent variable in the model so that the interpretation of the relationship between the dependent variable and whether a GP was present was that of a relative change in rate (consistent with the primary and secondary analyses for these outcomes). Outcomes that were expressed as proportions were not transformed so that the interpretation was that of an absolute change in proportion (again, consistent with the primary and secondary analyses).

The contamination-adjusted intention-to-treat analysis could not be undertaken for eight of the 21 outcomes. The instrument variable was not considered to be strictly exogenous in seven of these with the eighth being the gastrointestinal infections outcome for which a satisfactory model could not be arrived at for any analysis.

References

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3. McFadden D. Exogenicity test: a simple case. In: Lecture notes for Economics 240B, fall 2002. https://eml.berkeley.edu/~mcfadden/e240b_f02/chap24_test.pdf (viewed Mar 2020).
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5. Anderson TW. Estimating linear restrictions on regression coefficients for multivariate normal distributions. Ann Math Statist 1951; 22: 327-351.
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2. Changes to study protocol

Changes to outcome measures

We were unable to collect two secondary outcomes and added two secondary outcomes following trial registration. We had initially planned to measure the proportion of residents using enteral feeding throughout the trial, however, review of the data collection systems following trial commencement revealed that this data element was not being captured in the manner anticipated so was dropped from the evaluation. This was also the case for staff sick leave. The primary outcome of unplanned hospital transfers was initially planned to be collected only through the Resident Movement Summary database, however, initial project data quality monitoring identified that not all hospital transfers were being captured in this system. Instead, staff would also record these data in parallel data collection systems including incident reports lodged in the Amity Management System, and written entries in resident progress notes. We therefore expanded our data collection approach to include all three systems. In doing so, we were also able to capture data on whether the resident was actually admitted to the hospital that they had been transferred to and the number of days that resident spent in hospital. Thus we added these two outcomes as secondary measures.

The outcome of staff satisfaction with their employment was captured at two time points (once pre-intervention in 2012, and once post-intervention in 2015). We introduced the process measure of whether a GP was actually employed at the facility during each intervention period following trial registration.

Changes to data collection

GP out of hours calls data were only collated from sites for one of the retrospective data collection periods as no systematic approach was used to capture this outcome prior to this at participating sites. Multiple attempts at data extraction from facility databases were made throughout the stepped-wedge trial period and the prospective follow-up to test data linkage procedures from the multiple databases storing outcomes for this trial. Medication data from third party providers was unable to be extracted for one site, while two sites commenced and data quality checking found three sites to have data that were unreliable. The final data extraction was conducted in February 2017.

Changes to analysis approach

Data monitoring identified problems with data extraction for medications from two sites for the full retrospective period, one site for the full trial period, while one further site had no medication data that was able to be collected from the external provider. Data for the analgesic and dementia medication categories contained inconsistencies in classifications that could not be resolved, resulting in analyses being dropped for this outcome.

We used summative, site-level data for each block of the trial (eg, the total number of falls at the facility over the 9 week block) rather than resident-level data as we were unable to accurately link resident-level data between the different data collection systems. This was due to inconsistent use of unique resident identifiers across systems, combined with migration to a new data collection platform by the organisation part-way through the stepped-wedge part of this study. The decision to change from resident-level to facility-level analyses (as described above) was made subsequent to trial registration.

The instrumental variable analysis was not initially planned but became a viable option once it became clear that a number of sites were not able to employ a GP once they entered the intervention phase. Gastrointestinal infection outcomes could not be analysed in isolation using the mixed effects general linear model approach due to extreme skew in these outcomes that could not be resolved using data transformations. These were not pursued but were still included in the overall infections outcome.

Table 1. Primary and contamination-adjusted intention-to-treat analysis of outcomes, compared as incidence rate ratios*

	Mean number (SD), per site per nine-week block				Primary analysis			Auxiliary analysis	Contamination-adjusted intention-to-treat analysis	
	Stepped wedge trial period		Entire study							
Outcome	**Control**	**Intervention**	**Control**	**Intervention**	**IRR (95% CI)**	***P***	**ARR**	***P***	**IRR (95% CI)**	***P***
Occupied bed-days	6610 (2219)	6255 (1800)	6201 (2141)	6347 (1906)	—	—	—	—	—	—
Primary outcomes and related outcomes										
Falls	56 (25)	59 (25)	45 (24)	55 (24)	1.05 (0.94–1.18)	0.35	6.32	0.85	1.37 (1.20–1.58)	< 0.001
Fall-related fractures	1 (1)	1 (1)	0 (1)	1 (1)	1.54 (0.56–4.22)	0.40	0.37	0.27	NC	
Unplanned hospital transfers	19 (10)	14 (9)	17 (9)	13 (9)	0.81 (0.66–1.01)	0.06	–3.48	0.92	0.53 (0.43–0.66)	< 0.001
Unplanned hospital admissions	13 (7)	9 (6)	12 (7)	8 (6)	0.74 (0.56–0.96)	0.024	–2.97	0.88	0.52 (0.41–0.64)	< 0.001
Days in hospital	99 (66)	62 (51)	86 (58)	60 (51)	0.87 (0.79–0.97)	0.007	–13.2	0.88	0.44 (0.30–0.63)	< 0.001
Secondary outcomes										
Out-of-hours GP call-outs‡	16 (16)	15 (16)	16 (18)	13 (15)	0.84 (0.42–1.68)	0.61	4.67	0.86	0.54 (0.36–0.80)	0.002
Infections	20 (11)	25 (16)	18 (12)	23 (17)	1.42 (1.18–1.70)	< 0.001	8.71	0.86	1.22 (0.95–1.58)	0.11
Urinary tract	10 (5)	11 (8)	8 (5)	10 (7)	1.68 (1.29–2.20)	< 0.001	5.46	0.86	1.26 (0.97–1.62)	0.08
Gastrointestinal	1 (4)	2 (6)	2 (7)	2 (7)	NC	—	NC	—	NC	
Respiratory	9 (7)	12 (11)	9 (7)	11 (10)	1.23 (0.94–1.62)	0.12	3.75	0.84	1.17 (0.87–1.59)	0.31
Pressure areas	4 (4)	4 (3)	3 (3)	4 (4)	1.11 (0.71–1.74)	0.64	0.34	0.81	0.88 (0.65–1.19)	0.40
Skin tears	29 (17)	31 (23)	21 (15)	28 (19)	0.95 (0.81–1.10)	0.48	–1.89	0.64	NC	
Patient/family complaints	10 (9)	9 (11)	9 (8)	8 (9)	0.87 (0.42–1.76)	0.69	–0.44	0.87	0.46 (0.33–0.63)	< 0.001
Episodes of resident aggression	3 (3)	3 (2)	3 (3)	3 (2)	1.02 (0.65–1.59)	0.93	0.34	0.61	NC	
Deaths	6 (3)	6 (3)	6 (3)	6 (3)	1.31 (0.94–1.82)	0.12	1.67	0.47	NC	
Medication errors	5 (5)	13 (12)	3 (4)	12 (10)	5.11 (2.66–9.81)	< 0.001	15.2	0.25	NC	

ARR = absolute rate reduction; CI = confidence interval; IRR = incidence rate ratio; NC = not calculated: auxiliary ordinary least squares regression: $P < 0.80$.

Table 2. Primary and contamination-adjusted intention-to-treat analysis of outcomes, compared as differences in proportion or mean (absolute risk reduction)

	Absolute number of assessments and mean proportion (SD), or number (SD)				Primary analysis		Auxiliary analysis	Contamination-adjusted intention-to-treat analysis	
	Stepped wedge trial period			Entire study					
Outcome	**Control**	**Intervention**	*P*	**Intervention**	**ARR (95% CI)**	*P*	*P*	**ARR (95% CI)**	*P*
Primary outcome									
Polypharmacy, proportion of resident assessments*	4100/5395 76% (9%)	6681/9162 73% (7%)	8310/11 110 76% (10%)	15 118/20 493 74% (8%)	0 (–2 to 2)	0.89	0.60	NC†	
Secondary outcomes									
Medications per resident, mean*	9 (1)	8 (1)	8 (1)	8 (1)	–0.09 (–0.29 to 0.11)	0.37	0.77	NC†	
Proportion of resident assessments prescribed:*									
Psychotropics	3597/5395 66% (12%)	6505/9162 71% (8%)	7703/11 110 69% (13%)	14 287/20 493 69% (9%)	–1 (–2 to 1)	0.37	0.37	NC†	
“As required” medications	3749/5395 71% (17%)	6254/9162 69% (9%)	8361/11 110 75% (19%)	13 821/20 493 68% (11%)	–7 (–9 to –5)	< 0.001	0.83	–18 (–21 to –15)	< 0.001
Antibiotics	257/5395 5% (4%)	329/9162 3% (2%)	471/11 110 4% (3%)	819/20 493 4% (3%)	–0 (–1 to 0)	0.76	0.95	0 (–1 to 1)	0.76
Staff members leaving per assessment, proportion	459/6238 8% (3%)	661/8066 8% (8%)	969/12 647 7% (3%)	1402/20 098 7% (6%)	1 (–2 to 3)	0.62	0.81	1 (–1 to 3)	0.42

ARR = absolute rate reduction; IRR = incidence rate ratio; NA = not applicable; NC = not calculated: auxiliary ordinary least squares regression: $P < 0.80$; SD = standard deviation.

* These analyses exclude all data from two sites, and retrospective period data for another two sites. Data monitoring of third party provider pharmacy data at these sites identified inconsistencies during the study period; for one, the inconsistencies could not be resolved, while for two, the inconsistencies could be resolved from the commencement of the prospective data collection period.