THE AGED RESIDENTIAL CARE HEALTHCARE UTILISATION STUDY (ARCHUS): A MULTIDISCIPLINARY, CLUSTER RANDOMISED CONTROLLED TRIAL DESIGNED TO REDUCE ACUTE AVOIDABLE HOSPITALISATIONS FROM LONG TERM CARE FACILITIES

Connolly M.J. (Freemasons' Professor of Geriatric Medicine)[1,2],

Boyd M. (Gerontology Nurse Practitioner and Senior Lecturer)[1,2,3],

Broad J.B. (Senior Research Fellow)[1],

Kerse N. (Professor and Head of School of Population Health)[4],

Lumley T. (Professor of Biostatistics)[5],

Whitehead N. (Lecturer and Director of Nursing)[6]

Foster S. (Research Fellow)[1]

[1] Freemasons' Department of Geriatric Medicine, University of Auckland, PO Box 93 503, Takapuna, Auckland, New Zealand
[2] Waitemata District Health Board, PO Box 93 503, Auckland, New Zealand
[3] Department of Nursing, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand
[4] School of Population Health, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand
[5] Department of Statistics, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand
[6] Bethesda Care, 743 Great South Rd, Manukau City 2104, New Zealand

Corresponding Author: Professor Martin J Connolly, MD, FRCP, FRACP. Freemasons' Department of Geriatric Medicine, PO Box 93 503, Takapuna, Auckland, New Zealand

Tel: +64 (0)9 442 7146/7170

Fax: +64 (0)9 442 7166

Email: martin.connolly@waitematadhb.govt.nz

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ABSTRACT

Objective To assess effect of a complex, multidisciplinary intervention aimed at reducing avoidable acute hospitalisation of residents of residential aged care (RAC) facilities.

Design Cluster randomised controlled trial.

Setting RAC facilities with higher than expected hospitalisations in Auckland, New Zealand were recruited and randomised to intervention or control.

Participants 1998 residents of 18 intervention facilities and 18 control facilities.

Intervention A facility-based complex intervention of nine months duration. The intervention comprised gerontology nurse specialist (GNS)-led staff education, facility bench-marking, GNS resident review and multidisciplinary (geriatrician, primary-care physician, pharmacist, GNS and facility nurse) discussion of residents selected using standard criteria.

Main outcome measures Primary endpoint was avoidable hospitalisations. Secondary endpoints were all acute admissions, mortality and acute bed-days. Follow-up was for a total of 14 months.

Results The intervention did not impact main study endpoints: number of acute avoidable hospital admissions (RR = 1.07; 95% CI = 0.85 to 1.36; p=0.59) or mortality (RR = 1.11; 95% CI = 0.76 to 1.61; p=0.62).

Conclusions This multidisciplinary intervention, packaging selected case review and staff education had no overall impact on acute hospital admissions or mortality. This may have considerable implications for resourcing in the acute and RAC sectors in the face of population ageing.

Trial registration Australian and New Zealand Clinical Trials Registry (ACTRN12611000187943).

INTRODUCTION

Ageing populations mean that the health of older people is an increasingly important issue. Those aged over 65 years will comprise 23% (13% in 2011) of New Zealand's (NZ's) population by 2051, and the proportion over age 85 will double in 25 years,[1] markedly increasing NZ's care and healthcare expenditure,[2] Similar, or more advanced, ageing demographics exist throughout the OECD, raising sustainability issues for existing healthcare models, including acute care.[3]

Residential aged care (RAC) residents, often with complex comorbidity, are frequent, costly users of acute hospitals. In follow-up of our large 2008 cohort of Auckland RAC residents; the 'OPAL' study[4 5] 6% were hospitalised in the four weeks post-survey. Over 75% of the hospitalisations were acute. New ways to support RAC are needed to improve outcomes, including reducing acute avoidable hospitalisations which are potentially hazardous for frail older people.[6]

Quality of care for RAC populations depends on staff (especially qualified nurses and care-assistants), the facility, and services available.[7] These, in turn, relate to organisation of health systems, availability and quality of medical/ nursing workforce, number and training of care-assistants, and facility ownership (investor vs. not-for-profit).[7 8] Indicators useful in investigating RAC quality, for which between-facility variability is large,[7] relate to resident status, e.g. pressure sores, use of medication. Another measure of performance is hospitalisations,[8] and though there is no agreed definition of what constitutes an avoidable hospitalisation, some, perhaps most, acute hospitalisations are potentially avoidable,[9] with large variation in hospitalisation rates dependent on provider.[10] Older adults hospitalised acutely de-condition rapidly.[6] Hazards of hospitalisation include skin tears, pressure ulcers, falls, undernutrition, confusion, infections and new disability.[6 11] Transitions between care settings are disruptive particularly for those with dementia.

Rates of potentially avoidable hospitalisations – termed (by NZ Ministry of Health and others) Ambulatory Sensitive Hospitalisations (ASHs - e.g. from dehydration, pneumonia, falls, cardiac failure) - vary with patient and practice factors[9] and are a quality outcome for primary care and for RAC. Phase 2 of ARCHUS, reported here, aims to demonstrate reduced ASH rates of RAC residents. Phase 1 of ARCHUS modelled resident data from our 2008 OPAL study[4 5], discharge records from public hospitals and multivariate regression models to identify patient-related and facility-related factors predictive of ASHs. The model was applied to updated (2010) facility data to

identify Auckland RAC facilities with higher ASH rates [paper in preparation]. Phase 2 used the model to select RAC facilities with higher than average ASH rates.

METHODS

NZ recognises four levels of RAC:

- rest-home care (for those needing support with activities of daily living [ADLs], but not 24-hour nursing);
- private hospital care (for those requiring ADL assistance and 24-hour registered nurse availability);
- dementia care (secure rest-home care addressing safety issues);
- psychogeriatrics care (private hospitals for those with dementia plus behavioural difficulties or psychiatric illness plus physical frailty).

RAC facilities within all these levels were eligible for study inclusion**.** Phase 1 of the study employed resident data from the 2008 OPAL study[4 5] and discharge records from public acute hospitals to identify patient-related and facility-related factors predictive of acute ASH admissions. These were then applied to updated data in order to identify RAC facilities with higher rates of ASH admissions [paper in preparation].Facilities in greater Auckland are certified and supported by District Health Boards (DHBs) - geographically-defined health service providers that also provide acute hospital services.

Phase 2 (reported here) employed Phase 1's modelling, to target a facility-level intervention to RAC facilities with higher than average ASH rates. It was a cluster-randomised controlled trial (RCT) of an intervention in 36 greater Auckland RAC facilities (18 intervention,18 control matched by facility type & size; stratified by DHB). All residents in these facilities during the study were included, contributing hospital admission, death and person-time information. Methodology is already reported[12] but briefly the intervention combined several approaches to care, each previously reported to reduce acute admission from RAC:(a) Baseline facility assessment to identify areas of need and facility care plan developed by the interdisciplinary team); (b) monitoring and benchmarking of resident indicators linked to quality of care provided (falls, nutrition, restraint use, weight loss, UTIs, residents on $\geq$9 medications) - benchmarking was provided on three occasions during the intervention; (c) three 1-

hour multidisciplinary team (MDT) meetings - monthly for the first three months at each facility, including medication review by study geriatrician, GP, pharmacist & nurse manager. Typically, six residents were considered per meeting with priority given to new admissions, the recently hospitalised, those with recent 'incidents' (e.g. fall) and those on ≥9 medications; (d) gerontology education and clinical coaching for RAC nurses & care-givers including advanced (end-of-life) care planning, nutrition/ hydration, early detection of illness, falls prevention, end-stage dementia care, communication with families and practical aspects of care.

The GNS-led support/ education 'package' began with weekly visits and gradually reduced frequency through the 9-month intervention period aiming to foster facility independence prior to conclusion of active involvement. GNSs began the intervention with one new facility per month, to allow sufficient time for organisation and delivery of the intervention. Intervention package details are available from the authors. For specific residents the intervention also included consultation with community physiotherapy, speech-language therapy, palliative care/ hospice.GNS's time commitment was 20% across all intervention facilities. Residents in control facilities received usual DHB support, which did not include any of the elements any of (a-d) above. The study was approved by NZ Northern X Ethics Committee (NTY/10/11/090) as a facility-level intervention. Recruitment began December 2010; intervention began February 2011; follow-up was completed September 2012. Facility managers provided written, informed consent and facility information before randomisation. An advisory group, including DHB and RAC sector representatives, healthcare professionals, a Maori advisor and an Age Concern representative provided advice before and during the study. The trial was registered the on Australian New Zealand Clinical Trials Registry (ACTRN12611000187943) before randomisation.

Endpoints: ASHs were classified from a pre-specified list of diagnoses recorded as ICD codes (list available from authors) in routinely-collected public hospital admission records held by the Ministry of Health using the NHI (unique national health identifier for all NZ health service users). Facilities supplied NHIs and minimal other resident information monthly during the study. Analyses of effectiveness used ASH admissions as the primary endpoint (using the first three ICD-10 diagnostic fields - list available from authors). Secondary endpoints were all acute admissions, mortality and acute bed-days. We conducted three sensitivity analyses: 1) using only the first diagnosis code to identify ASHs with re-randomisation analyses; 2) time-to-event analyses (Kaplan-Meier); 3) poisson regression models adjusted for facility and resident co-variates (facility type (combined rest-home &

hospital /rest-home), DHB, nursing staff tertile, for profit status, after-hours GP cover, distance from hospital, bed-type (rest-home, dementia, private hospital, short-term, other), 5-yr age group & gender and with offset of follow-up days).

Power: With 18 facilities per group, each with 14 months' follow-up, an average of 38 beds per facility and 90% bed occupancy, we expected 1500 resident-years follow-up. A sample size of 1400 resident-years was originally anticipated to give 80% power ($p \leq 0.05$) to detect 25% reduction in rate of ASH hospitalisations in the intervention group vs. the control group when an event rate of 60 events per 100 years was expected. However, the observed event rate in another cohort after trial commencement was lower, and power estimates were recalculated. Revised power was estimated at 53%, considering: (a) inflated sample size as the design effect of 2.0 allowed for moderate intra-cluster correlation for hospitalisation rates of 0.025 [12]; (b) a rate of 35 ASH admissions per 100 resident years in control facilities vs. 26 ASH admissions in intervention facilities, assuming a Poisson distribution where the mean equals the variance. Control event rate was estimated from re-analysis of other cohorts[12]. However, we anticipated improved power because: facilities were chosen (modelling - Phase 1) for their higher event rates (e.g. event rate of 0.40 would give power of 0.67); short-stay residents (under-represented in OPAL-based rates) have a higher event rate; adjustment for covariates in our analysis was anticipated to reduce confidence intervals around effect size.

Randomisation: Facility randomisation was conducted (using random number generation via 'Excel'), by JBB a non-clinical investigator with no facility contact, stratified by DHB and paired by care types (rest home only, or a mix of rest home [lower level of care/dependency] and 'hospital' [high-level of care/ dependency] beds) and size where possible. Stratification by DHB was employed as these DHBs differ demographically and to balance workload across the DHB-based GNSs. Care was taken to blind the main investigators to facility identification wherever possible.[12]

Analyses: Analyses of effectiveness compared the rate of ASH admissions and other main endpoints over the sum of the follow-up time of all notified residents. Re-randomisation tests were used in which each pair of facilities (as initially presented for randomisation) was re-randomised many times, and a null distribution of effects obtained. Confidence intervals were derived from the 2.5^{th} and 97.5^{th} centiles multiplied by the relative risk.[13] This method was chosen over negative binomial models (originally planned), to yield unbiased estimates of treatment effect in the presence of covariance arising from the hierarchical design and clustered treatment.[13]

We also plotted time to first ASH admission and time to death using unadjusted log-rank methods. Resident-based sensitivity analyses used poisson regression models for admission counts, linear regressions for acute bed-days, and proportional hazards models for time to death, incorporating available facility- and resident-level co-variates. All results were analysed on an "intention to treat" basis, and tests of significance two-tailed.

Sub-group analyses to check for effects that differed from the overall treatment effect were performed for the following: facilities classed as charitable; religious or welfare facilities vs. for “for profit” facilities; facilities that have only rest-home beds vs. those with both rest-home and hospital beds; for the three DHBs separately; facilities with above-median ASH rates (from participating facilities before study commencement) vs. those below-median; facilities according to their level of nursing cover per bed (under 5 hours/week, 5 to 9 hours per week, and 10+ hours per week); facilities providing after-hours primary care cover through either their usual GP or a contracted after-hours primary care provider vs. those without such cover (effectively using ambulance and emergency department for after-hours primary care). We also undertook sub-group analyses by the following groups of residents: long-stay vs. short-term (e.g. respite or palliative care) residents; rest-home care type vs. hospital care type; and if present in the facility at the start date vs. admitted later during the study.

For the purpose of informing future studies planning a cluster design, we estimated the variance inflation factor from the variance about the estimated treatment effects reported from two generalised linear mixed models with adjustment for DHB, with and then without facility as a random effect.

RESULTS

Figure 1 summarises recruitment, retention and outcomes. Of 2011 residents originally enrolled, we validated the identity and data of 1998 (99.4%) against their NHI. One control facility withdrew before follow-up was complete. Fifty-two of a planned 54 MDT meetings were held; 281 case discussions (263 residents, 23.4% of the intervention arm resident population) occurred. All GNS visits occurred as per protocol. Table 1 summarises baseline characteristics of residents and of facilities.

In all, 901 admissions (82% of 1099 acute admissions) were classified as ASHs: 234 falls/ fractures, 230 pneumonia/ other respiratory infections, 175 dehydration/volume depletion, 165 urinary infection, and 116 congestive heart failure; and 419 deaths were recorded during follow-up. There were no differences between intervention and control groups in rates of ASH admission (RR = 1.07; 95% CI =

0.85-1.36; p=0.59), total acute admission (RR = 1.02; 95% CI = 0.83-1.26; p =0.84) or mortality (RR = 1.11; 95% CI = 0.76-1.61; p=0.62) (Table 2 & Fig 2) nor, (Fig 3), in time to ASH admission or death. There were no differences in acute hospital bed-days occupied, except in the sub-group of residents from facilities with below median ASH rates pre-study (cf. all facilities) who had lower occupied acute hospital bed-days than those from facilities with above-median ASH rates (RR=0.71, 95% CI=0.51-0.98; p=0.039). No other sub-group or sensitivity analyses revealed any difference in treatment effect. Design effect was estimated as 3.67 with a mean of 55.5 residents per facility during the study.

DISCUSSION

ARCHUS was a well matched, well conducted RCT. It demonstrated no effect (beneficial or harmful) on its major end points of ASH admissions, total acute hospital admissions, bed-days, or mortality. Confidence intervals about the relative risks ruled out a reduction of $\geq$20% in ASH admissions and deaths. It can thus be described as a robustly neutral study.

Our study has many strengths. It was adequately powered, and had excellent facility 'buy-in' and retention and almost complete (99.4%) subject matching to resident outcomes. Its intervention was structured yet flexible, and each aspect of the intervention was evidence-based. However, it has weaknesses. We did not test hospital *presentations* to emergency units, though this may more directly measure RAC staff decisions. The 9-month intervention or 14-month follow-up periods may have been too short. Only 23% of residents were discussed in MDT meetings, and though those discussed were selected for clinical acuity, this may have limited the intervention's effectiveness. It is possible that control facilities, responding to their perception of study design, may have changed their behaviour. Our education package, aimed to improve carers' ability to recognise "sick" residents, may have resulted in some residents being seen as ill and hospitalised when they otherwise would not have been. Thirteen facilities identified in Phase 1 declined to participate, reducing the benefit of facility targeting. In contrast to Kane,[14] we were unable to employ nurse *practitioners* (a scarce NZ resource). Most nurse practitioners are authorised to prescribe medication, and thus can intervene quickly e.g. in treatment of infection, heart failure, or adverse drug reactions.

There is literature evidence that intervention in RAC may result in improved care and/or reduced hospitalisation. These interventions have comprised: MDTs providing an integrated care approach;[15]

more skilled RAC staff for assessment/ recognition of illness;[9 14-16] education and clinical coaching;[15 17] improved care co-ordination by e.g. nurse practitioners; better assessment of acute/ sub-acute changes in condition;[18] nutritional screening/intervention;[19] advance care planning;[20] and medication review.[21] It was based on these studies that we developed the ARCHUS intervention.

However, most of this evidence comes from recommendations, or from observational, retrospective cohort, or non-randomised controlled studies, rather than RCTs,[9 14 15 19 20] and any RCT-based evidence of improvement in outcomes does not include assessment of admissions.[17 18 21] A 2008 review of evidence on reducing hospitalisations from RAC[16] commented that clinical literature tends to focus on disease-specific interventions whilst health service research literature examines large administrative databases. Systematic reviews of RCTs in RAC have identified largely non-complex, topic-specific interventions (e.g. falls, influenza, mobility)[22] and shown that avoidable hospitalisations do not feature as a primary outcome for multidisciplinary interventions.[23] A 2012 review aimed at avoidable hospitalisations from long-term care[24] commented that the measures studied are unvalidated in LTC settings. RCTs of medication review[25 26] did not find reductions in hospitalisations.

Evercare, a large, controlled, non-randomised US study of nurse practitioner care in RAC, reduced hospitalisations.[14] Similar results were reported in a Canadian unblinded 'before/after' study,[27] and from INTERACT II,[15] a partially controlled, non-randomised, quality improvement intervention. RAC interventions (again observational studies, retrospective cohort- or case-control studies) including better preventive care and emphasis on managing acute illness in place, report improved health outcomes.[28] Higher quality (RCT) evidence applies to functional outcomes[29] and falls[30] but apart from large-scale model change, reductions in hospitalisations are rare. Given that our GNSs were visiting intervention (not control) facilities frequently we considered the possibility of lower attainment of residents with short stays (and thus possibly higher acute admission rates and/or mortality) from control facilities. Thus, after study completion, our project manager (SF) visited a selection of control facilities with the reported lowest 'turn-over' of residents, examining resident records. No evidence to support this possibility was found, though such retrospective checks are imperfect. Our intervention took place in RAC facilities which had routine *clinical* input from GNSs, albeit in a non-targeted, less intense manner. This prompted us to consider whether baseline rates for our outcome measures (Fig. 2) may have already been optimised, or near-optimised, before ARCHUS. Some comparator data, albeit from nursing homes - more closely comparable with private hospital than rest home care -

are available in the literature (directly or by simple calculation), and while it is difficult to reliably compare data from different jurisdictions, care systems and time periods, we do not feel that there is strong evidence to support that concern[9 17 19] though one study[9] did report higher baseline hospitalisations from RAC facilities selected for their high hospitalisation rates (comparable with our Phase 1 targeting). A study from Australia (perhaps more similar to NZ than most jurisdictions) reported higher baseline hospitalisations and hospital bed-days than the current study.[24]

The sole significant difference on subgroup analyses - lower occupied hospital bed-days for residents from intervention group facilities with previously below-median ASH rates – is intriguing. Given the level of significance (p=0.039) this may be a random effect of multiple testing. We considered that lower previous ASH rates might be a marker for better staffing levels and thus greater potential to respond to the intervention. However, analysis of registered nurse/ carer staffing levels by facility revealed no relationship with prior ASH rates or ARCHUS outcomes. Nonetheless, we tentatively suggest that facility ethos, including willingness to change (for which we have no measure), might have been related to previously lower ASH rates and to capacity to benefit from interventions.

We believe the findings of ARCHUS are genuine, robust and widely applicable. The implications of this in the face of population ageing are several and not mutually exclusive. First, if our findings are confirmed by others, we may have to conclude that it is not possible to reduce ASHs from RAC and that we must increase acute provision. The resource implications of this in the acute sector would be enormous. Second, it may be that it is not possible (or very difficult) to reduce ASHs from RAC by an outreach model and that we need to increase RAC facility resource.[7] Given the low staffing and other resource commonly devoted to RAC this would also be expensive. Third, it may be that we need to intervene 'harder and smarter' e.g. on-site nurse practitioners (as opposed to nurse specialists) and/ or targeting specific diagnoses for whom evidence, from the literature or (in terms of admission predictors) from ARCHUS Phase 1, is stronger. Finally, we may need to intervene more intensively or for longer (again expensive); though there was no evidence from our survival analyses of any change in effect over time, it is possible that a longer or more intensive intervention would have fostered greater relationship-building between RAC and hospital-based staff, with consequent clinical benefits.

In summary, this RCT provides no evidence that multidisciplinary, non-disease specific intervention into RAC results in overall reduction in acute hospitalisations, mortality or hospital bed-days. There remain unanswered questions over type and duration of interventions - subjects for future research.

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All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that: (1) MJC, MB, JBB, NK, TL, NW and SF have support from the University of Auckland and the Health Research Council of New Zealand for the submitted work; (2) MJC, MB, JBB, NK, TL, NW and SF have no relationships with other organisations that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) MJC, MB, JBB, NK, TL, NW and SF have no non-financial interests that may be relevant to the submitted work.

The funders of the ARCHUS study had no influence on study design data collection, analysis or interpretation, and no influence on manuscript preparation.

All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and accuracy of the data analysis.

Participants (RAC facilities) did not give informed consent for data sharing and, despite anonymisation of the data, the risk of facility identification is moderate to high. The authors would however consider requests for data sharing contingent upon further ethical approvals.

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Table 1 Baseline characteristics of facilities and residents

	N		%	
	Intervention	**Control**	**Intervention**	**Control**
Facility characteristics				
Total	**18**	**18**	**100.0**	**100.0**
Rest home only	13	13	72.2	72.2
Rest home and hospital combined	5	5	27.8	27.8
Facility (or wing/unit) size				
3 – 29 beds	5	6	27.8	33.3
30 – 59 beds	9	11	50.0	61.1
60+ beds	4	1	22.2	5.6
Beds within participating facilities				
Total	**754**	**607**	**100.0**	**100.0**
Auckland DHB	230	186	30.5	30.6
Counties Manukau DHB	230	236	30.5	38.9
Waitemata DHB	294	185	39.0	30.5
In facilities with rest-home beds only	500	382	66.3	62.9
In facilities with both RH & PH beds	254	225	33.7	37.1
RH beds in mixed-bed facilities	109	160		
PH beds in mixed-bed facilities	145	65		
Resident characteristics				
Enrolled and matched	**1,123**	**875**	**100.0**	**100.0**
Residents' care levels				
Long-stay rest home care (incl. YPD)	796	675	70.9	77.1
Long-stay hospital level care	216	134	19.2	15.3
Short-stay care*	85	37	7.6	4.2
Dementia care	11	22	1.0	2.5
Other, unstated	15	7	1.3	0.8
Gender and age				
All women	775	633	69.0	72.3
Under 65 years	37	34	3.3	3.9
65 – 74 years	72	61	6.4	7.0
75 – 84 years	214	176	19.1	20.1
85 – 94 years	393	294	35.0	33.6
95+ years	59	68	5.3	7.8
All men	348	242	31.0	27.7
Under 65 years	35	32	3.1	3.6
65 – 74 years	59	37	5.3	4.2
75 – 84 years	117	79	10.4	9.0
85 – 94 years	130	85	11.6	9.7
95+ years	7	9	0.6	1.0
Follow up years				
Total	**888.3**	**734.5**		
Mean per facility	33.5	43.5		
Mean per resident	0.79	0.84		

YPD = Young Physically Disabled
* includes End of Life, 'Primary Options' (NZ alternative to acute public hospitalisation) for Acute Care and Respite care
DHB = District Health Board
RH = rest home
PH = private hospital

Table 2 Main endpoints and associated treatment effects

	Intv'n		Control		RR*	95% CIs	p-value
	N	rate	N	rate			
End point							
Acute ASH admissions:							
Using 3 ICD codes	509	0.57	392	0.53	1.07	0.85 to 1.36	0.59
Using 1 ICD code	443	0.50	307	0.42	1.19	0.94 to 1.51	0.16
All acute admissions	608	0.68	491	0.67	1.02	0.83 to 1.26	0.84
All deaths	240	0.27	179	0.24	1.11	0.76 to 1.61	0.62
Acute hospital bed-days	3,716	4.18	3,239	4.41	0.95	0.81 to 1.10	0.51

*RR = relative risk, 95%CI = 95% confidence intervals

Rates expressed as per person year

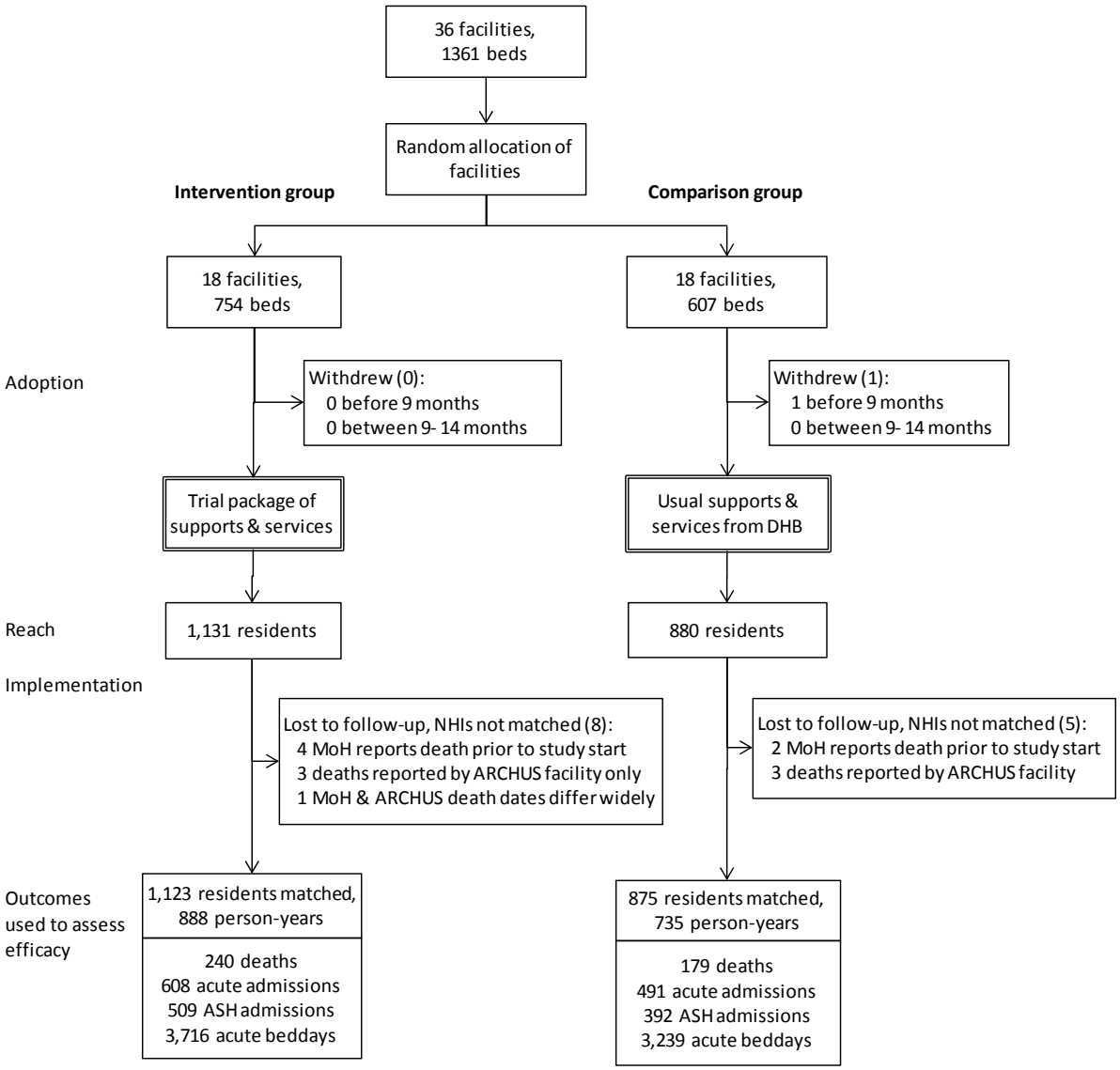


Figure 1 **Flowchart of the ARCHUS trial: enrolment, allocation, follow-up and end points**

	N		Rate per follow-up year		
	Intv'n	Control	Intv'n	Control	p value
Acute ASH admissions	509	392	0.57	0.53	0.59
All acute admissions	608	491	0.68	0.67	0.84
All deaths	240	179	0.27	0.24	0.62
Acute hospital bed-days	3,716	3,239	4.18	4.41	0.51

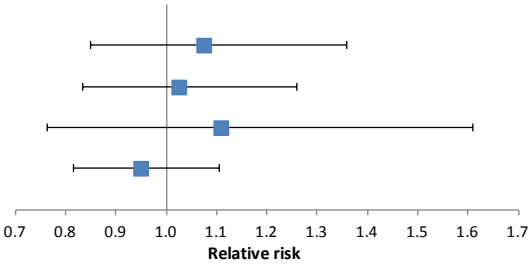
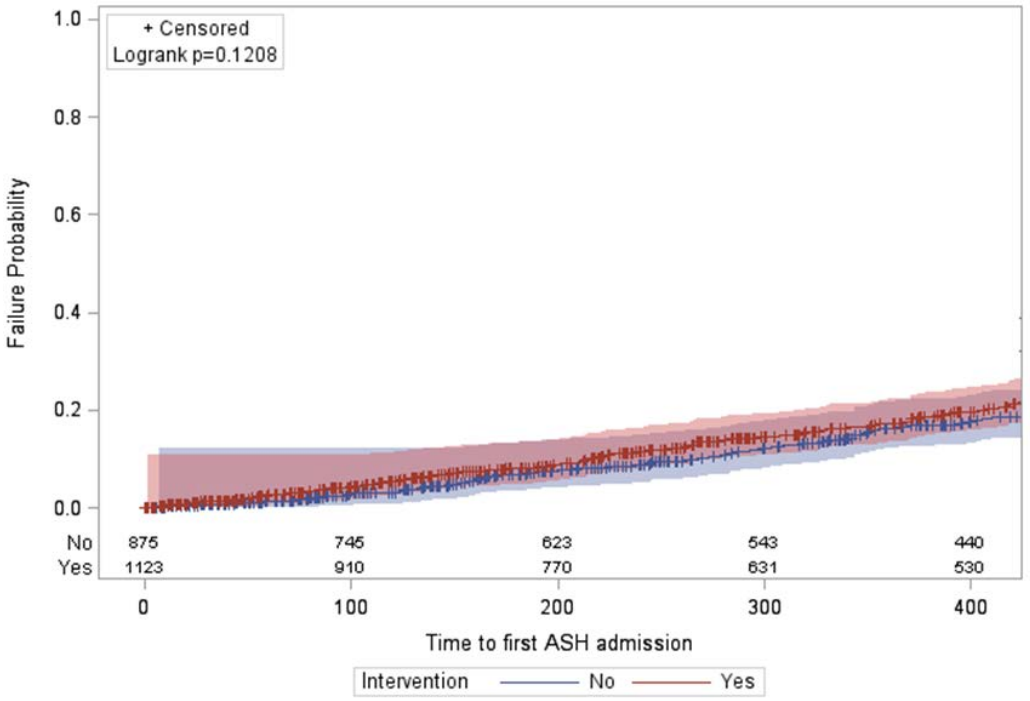


Figure 2 **Forest plot of treatment effect by end point.**
Lines represent 95% confidence intervals about the relative risk

a) Time to first ASH admission



b) Time to death

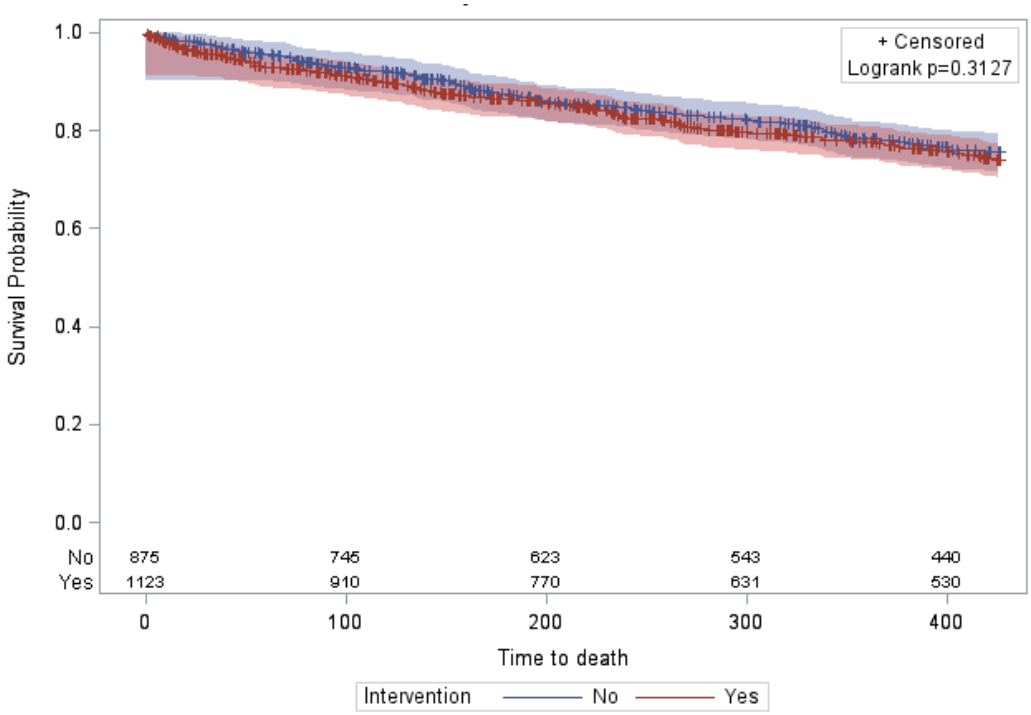


Figure 3 **Plots of time from study start to a) first ASH admission and b) death (unadjusted for follow-up time or covariates)**