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The effect of advanced recovery room care on postoperative outcomes in moderate-risk surgical patients: a multi-centre feasibility study

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Summary

Postoperative complications are common and may be under-recognised. It has been suggested that enhanced postoperative care in the recovery room may reduce in-hospital complications in moderate- and high-risk surgical patients. We investigated the feasibility of providing advanced recovery room care for 12–18 hours postoperatively in the post-anaesthesia care unit. The primary hypothesis was that a clinical trial of advanced recovery room care was feasible. The secondary hypothesis was that this model may have a sustained impact on postoperative in-hospital and post-discharge events. This was a multicentre, prospective, feasibility before-and-after trial of moderate-risk patients (predicted 30-day mortality of 1–4%) undergoing non-cardiac surgery and who were scheduled for postoperative ward care. Patients were managed using defined assessment checklists and goals of care in an advanced recovery room care setting in the immediate postoperative period. This utilised existing post-anaesthesia care unit infrastructure and staffing, but extended care until the morning of the first postoperative day. The advanced recovery room care trial was deemed feasible, as defined by the recruitment and per protocol management of > 120 patients. However, in a specialised cancer centre recruitment was slow due to low rates of eligibility according to narrow inclusion criteria. At a rural site, advanced recovery room care could not be commenced due to logistical issues in establishing a new model of care. A definitive randomised controlled trial of advanced recovery room care appears feasible and, based on the indicative data on outcomes, we believe this is warranted.

Postoperative complications are common and result in increased healthcare costs [1,2]. Recent data suggest the magnitude of this problem is under-recognised, especially very early after surgery [3]. The rising global volume of surgery [4], ageing populations and increasing frequency of comorbidities, all suggest that postoperative complications will increase substantially in the future [5]; this will have a negative impact on patient-centred outcomes (including quality of life [6]) and will result in increased healthcare expenditure. There is evidence that patients who have adverse events (e.g. hypotension) in the recovery room (also known as the post-anaesthesia care unit (PACU)) are more likely to require interventions on the postoperative ward [7]. In fact, postoperative hypotension is associated with an increased incidence of acute kidney injury, myocardial infarction and mortality [8]. Studies have shown that enhanced recovery room interventions may have positive effects on the incidence of in-hospital complications in moderate- and high-risk patients [9], and on intensive care (ICU) admission [10,11]. This suggests that a model of extended recovery room care

warrants further exploration. A recent single-centre retrospective analysis of early brief high-dependency care in moderate-risk patients (predicted 30-day mortality of 1–4%) was associated with a reduction in postoperative complications [12]. Furthermore, recent discussions in the United Kingdom have highlighted the potential need for mid-level postoperative care, sitting between ward and ICU levels of care [13]. Therefore, we proposed a model of advanced recovery room care (ARRC) using existing PACU infrastructure, including personnel and the range of care usually involved in the PACU, but extended until the first postoperative day. The name ARRC was deliberately chosen to emphasise its links to recovery room staff and capacity, with 'advanced' chosen to highlight the emphasis on consistent processes (rather than, for example, 'extended'). We conducted a multi-centre pilot before-and-after feasibility study to test this model of care. The general aim of the intervention was to improve the recognition and treatment of complications, which might subsequently reduce postoperative morbidity and healthcare costs. The primary hypothesis was that a clinical trial of ARRC was feasible, and thus would potentially allow a subsequent larger trial to be conducted [14]. An exploratory secondary hypothesis was that this model may have a sustained impact on postoperative in-hospital and post-discharge events.

Methods

Ethics committee approval was obtained, with approval for opt-out consent and the trial was registered prospectively. This study was a multi-centre, prospective, feasibility trial with before-and-after study cohorts consisting of moderate-risk patients who were listed for non-neurosurgical and non-cardiac surgery and were scheduled to receive postoperative ward-level care. Moderate risk was defined as a 30-day mortality of 1–4% predicted by the American College of Surgeons National Surgery Quality Improvement Program (NSQIP) risk stratification tool; this incorporates patient and surgical factors to determine the probability of postoperative events [15]. Other inclusion criteria were: age ≥ 18 y; predicted duration of hospital stay ≥ 2 days (to allow in-hospital assessment of quality of recovery); good English comprehension; and likely availability for follow-up at 90 days.

Recruitment of patients occurred based on surgery conducted from Monday to Thursday for each period, in order to avoid weekend staffing. To test feasibility, we anticipated two phases of about 5 weeks each, in order to test data collection during usual care, and then to test both clinical implementation and data collection in the intervention phase. We anticipated we would test feasibility based on a pragmatic, convenient sample size that reflected each of the participating hospitals' workload and capacity. We estimated at least 120 patients overall would be adequate to test feasibility. Three different types of hospitals participated in this study: the Royal Adelaide

Hospital (RAH), a large metropolitan tertiary centre which treats a wide range of adult patients requiring emergency and elective surgery, aimed to recruit three to four patients per day, 4 days a week; the Peter MacCallum Cancer Centre (PMAC), a tertiary hospital largely treating cancer patients requiring elective surgery, with emergency and ICU patients largely cared for in an adjacent large public hospital, aimed to recruit one to two patients per day, four days a week; and Lismore Base Hospital (LBH), a regional base hospital with an intensive care unit, aimed to recruit two to three patients per day, 4 days a week. At RAH and LBH, an experienced trials nurse screened theatre lists for potentially suitable patients. At PMAC, all patients attending the pre-anaesthetic clinic and those on the weekly theatre lists were screened by an anaesthetist and two experienced research nurses.

There were three defined time periods within this feasibility trial: a 5-8 week before-period; then a training period to establish ARRC procedures; and then a 5–8 week after-period. Patients were initially treated in the recovery room and then transferred to the ARRC area, an existing space within, or adjacent to, the recovery room. Advanced recovery room care utilised the same range of staff and care usually involved in the recovery room. Care during the day was primarily from the pool of anaesthetists in the theatre complex, with evening care until 22:00 provided by a rostered anaesthetist or senior registrar. Overnight care was provided by registrars already available for emergency cases, supported by a specialist anaesthetist on remote call. Nursing ratios were 2:3 (RAH) and 1:1 (PMAC) for the purposes of the trial and data collection, but were envisaged to be in the order of 1:2 to 1:3 going forwards. The range of care available included continuous invasive cardiovascular monitoring and administration of vasopressors, but excluded invasive or non-invasive ventilation (with the exception of pre-existing continuous positive airway pressure (CPAP) therapy). The level of monitoring was left to the discretion of the attending medical staff, as was the choice of treatment of any identified postoperative complication or medical issue (e.g. hypotension, desaturation, uncontrolled postoperative pain, bleeding etc.).

In addition to standard recovery room care, there were some specific additions to ARRC, aligning with the quality principle of consistency in care. Patients were reviewed regularly by an anaesthetist (hourly for the first 3 h, then three-hourly until 22:00), and thereafter as requested by nursing staff. A 19-point checklist (see online Supporting Information Fig. S1) was used at each review, which assessed key parameters such as cardiorespiratory vital signs, urine output, pain scores and blood glucose, with specific focus on the criteria for ward-care escalation (such as calling the medical emergency response team (MERT)) [16]. Care escalation to the MERT is part of the defined

standards for Australian healthcare, and criteria for escalation are consistent across hospitals (see online Supporting Information Fig. S2). However, MERT escalation was not utilised as part of ARRC, as specialised staff were available to manage these situations. The checklist was used to identify abnormal parameters, and required clinicians to record the treatment instituted for each. This ensured identified problems were not left unnoticed, and assisted other clinicians who may subsequently takeover care. Other medical staff from surgery or internal medicine were available for issues within their specific area of expertise. The goal was to have all parameters within the normal physiologic range for ward-level care by the morning of the first postoperative day. In the morning, patients were reviewed by an anaesthetist, the checklist again completed, and then patients were handed over to ward medical and nursing staff. If a patient was determined to be unsuitable for ward-level care, additional treatment was instituted. The patient was then either planned for review later that morning, or a referral was made to ICU for ongoing management; this was because ARRC was limited to managing patients within the first 24 h of their surgery.

Patients were followed up daily as in-patients, with written consent occurring at postoperative day 2 or the most suitable later opportunity. This was then followed by assessment of the quality of recovery score (QoR-15) [17]. Other trial endpoints were recorded from case notes and by telephone follow-up conducted at postoperative day 90.

The primary outcome measure was the feasibility of recruitment and postoperative follow up of a total of 120 patients. Exploratory in-hospital outcome measures also assessed included: the number of patients meeting MERT escalation criteria; incidence of unplanned ICU admissions; quality of recovery scores; duration of hospital stay; and 90-day mortality. Exploratory post-discharge outcome measures were also investigated and included: quality of life at postoperative day 90 (EQ-5D-5L, summed scores from all domains) [18]; days alive and out of hospital; and hospital readmissions. As this was an exploratory study with the primary endpoint being feasibility, no formal sample size calculation was performed. In line with guidelines for feasibility trials [19], data for secondary endpoints are reported descriptively, without formal statistical testing.

Results

A total of 200 patients were recruited. The proportion of patients who met exclusion criteria for the study varied between sites, and was dependent on the hospital case-mix and recruitment method used (Figs. 1–3). At RAH, experienced trials nurses had rates of exclusion of 74/146 (51%) and 43/98 (44%) for the before and after periods respectively. The most common exclusion criteria were:

NSQIP scores being out of range (often too low); and patient unwillingness to participate. At PMAC, all patients who attending the pre-anaesthetic clinic and/or were on a theatre list were screened, reflecting the high numbers screened but excluded. Once again, the most common exclusion criterion at PMAC was NSQIP scores being out of range.

Of those patients recruited, 126 were recruited at the RAH (April 2018 to July 2018: 71 patients in the 5-week before-period, and 55 patients in the 5-week after-period) and 40 patients were recruited at PMAC (August 2018 to January 2019; 24 patients in the 8-week before-period and 16 patients in the 8-week after-period). Before- and after-periods were separated by a 4-week training period at both hospitals. Although LBH recruited 34 patients in the 8-week before-period (October 2018 to December 2018) it was not possible to commence the training and after-period within the timeframes set for the trial; the data from this site were, therefore, excluded from analysis. Patient characteristics are shown in Table 1. Overall, patients were at the lower end of the moderate-risk range and were predominantly ASA physical status 3. There was reasonable matching in the before- and after-periods at both sites. There was reasonable within-site variation in types of surgery, but substantial between-site variation, reflecting the individual hospitals' roles, with the absence of emergency, vascular and orthopaedic surgery at PMAC being the most noticeable difference.

Follow-up rates at 90 days for the before- and after-periods were 68/71 (94%) and 53/55 (96%) for RAH and 24/24 (100%) and 16/16 (100%) for PMAC respectively. These follow-up rates suggest that the ARRC trial was feasible, with > 120 patients recruited and followed up at 90 days. However, recruitment was slow at PMAC with many patients being ineligible for exclusion for the reasons discussed earlier.

Patient review and completion of the checklist per protocol occurred in 220/246 (88%) and 84 of 123 (68%) of scheduled reviews at RAH and PMAC, respectively. The most common time for a missed review at RAH was in the late afternoon or early evening, around the time of elective list completion and transition to after-hours staffing. The compliance with checklist completion at PMAC was much lower in the final two weeks of data collection in January 2019 which occurred after a break in recruitment due to operating suite closure for the December holiday period. This highlights the importance of lead-in training periods and continuity in research protocols.

A number of postoperative events were measured in this study, reflecting its exploratory nature (Table 2). Serious in-hospital adverse events, as defined by patients meeting the criteria for care

escalation to a MERT call, were very common. The predominant groups of adverse events within the RAH cohort were as follow: haemodynamic (blood pressure and fluid)-related: 27/55 patients (49%); respiratory-related 4/55 patients (7%); and pain-related: 3 patients (5%).

Discussion

We have shown that a trial of advanced recovery room care is feasible in a tertiary hospital such as RAH, that has a broad case-mix and relatively large patient numbers. Although recruitment of patients at PMAC (a smaller specialist cancer centre) was possible, many patients were not suitable, because of the calculated patient risk was either too low or too high. The case-mix of PMAC is not typical of many hospitals and the baseline data on outcomes may have been affected by off-site management of potentially eligible patients in the HDU/ICU situated in a co-located institution.

It was not feasible to introduce ARRC at LBH, a regional hospital, for logistical reasons primarily related to a small pool of anaesthetic and nursing staff available to be redeployed to night duty. In addition, there were concerns expressed at this and other sites explored for inclusion in the trial about commitment of resources to a trial in the absence of clear evidence of unmet need and benefit of the proposed model. However, discussions with clinicians in other hospitals suggest these issues can be overcome. This study also suggests that the clinical application of the ARRC model is feasible: PMAC has introduced a version of this model into routine clinical practice and RAH is introducing a larger unit for ARRC (up to 10 beds). This suggests that the AARC model is cost-effective and has wide clinical support. Discussions with other hospitals have revealed enthusiasm for this approach, and suggest that staffing and infrastructure challenges can be overcome.

The proportion of patients screened but excluded was dependent on the methodology used and case-mix of the recruiting site. At RAH skilled trials staff reviewed theatre lists shortly before scheduled surgery with subsequent formal screening of likely candidates. This led to fairly low rates of exclusion, in part because of access to contemporary detailed data on the proposed surgery, expected duration of stay, patient comorbidities and English comprehension. At PMAC, all patients who attended the pre-anaesthetic clinic and/or were scheduled on weekly theatre lists were screened, with only a small proportion proving suitable for inclusion. It was notable that the pre-operative calculation of NSQIP scores was not routine practice in either hospital. Trials staff reported that there may have been a learning component at judging likely NSQIP scores. In future trials, there would be merit in all patients being formally risk scored early in the assessment period for potential

surgery; this is something which is considered a high priority in improving peri-operative health systems outcomes in Australia [20].

It was acknowledged by the hospitals involved in this study that the recovery room infrastructure necessary for ARRC was already in place, but tended to be underutilised out of hours and could therefore accommodate the patients receiving ARRC. Modest adaptions for patient care, such as lighting control, bathroom facilities and visitor access were considered important by patients and their families, nursing and medical staff.

There was reasonable within-site group matching of factors potentially associated with complications and outcome, such as predicted mortality, comorbidities, duration of surgery and emergency surgery. However, at RAH, in the after-group there was a trend towards a greater risk of mortality (related to three cases having conservative surgical management and palliative care due to disease state). This may have been due to RAH having a greater proportion of emergency surgical cases and a longer mean duration of surgery, both of which are factors known to adversely affect outcome [21, 22]. Regardless, this suggests that group matching is unlikely to be a major confounding factor in a before-and-after design.

The patients recruited to the study were largely in the lower-half of the moderate risk range. Despite this, the number of MERT-level events and 90-day re-admission rates at RAH were high. It was noted that for some surgeries such as arthroplasty, hysterectomy and colorectal resections, patients often did not reach the threshold of 1% NSQIP-determined mortality, and hence were not included in the trial. However, clinical opinion was that many of these cases would have had an early risk of mortality that was similar to those in the 1–4% range. Broadening the definition for moderate risk to an NSQIP-determined mortality risk of 0.7%–5.0% would capture this case-mix and may better reflect the views of clinicians involved in the trial as to which patients might benefit from extended high acuity postoperative care. Recent Australian data have confirmed that the NSQIP risk calculator can be adapted to suit the Australian population, and its use is expanding with at least seven Australian hospitals currently enrolled in the programme [23].

This was a small exploratory trial and as such, the outcome data on adverse events and outcomes must be interpreted with caution. The most striking of the secondary outcomes was the very high incidence of early serious complications, as defined by triggering a call for the MERT. The adverse event data from RAH have been reported previously [3], and suggested that these events

predominantly occurred early after discharge from the recovery room, often after hours, and were usually not detected or treated, with standard ward observation regimens. A number of studies have shown that postoperative adverse events are common in hospital [2,24] especially in older patients (who made up the majority of patients in this study). However, there is increasing recognition of the significance of problems such as even brief periods of hypotension [25], which was the most common adverse event at RAH. The limited treatment options for hypotension available on wards (largely fluid administration), concerns about excess fluid administration postoperatively [26] and the capacity to evaluate and treat hypotension with approaches such as vasopressors, all suggest that a higher acuity postoperative unit is well-suited to these patients. This aligns with the retrospective data of Swart et al. [12] and the prospective data from Eichenberger et al. [9] (albeit with a mix of higher and moderate risk patients) which suggested a prolonged positive benefit from early high-acuity care. In contrast, a recent systematic review [27] and large international cohort study [28] did not show evidence of survival benefit from a three-tier model of care that included ward-level care, surgical special care units and ICUs. However, this is likely to represent a higher-risk patient cohort, rather than the moderate-risk patients often cared for in the general ward. Furthermore, outcomes such as adverse events and re-admissions may be more sensitive indicators of the benefits of early enhanced care than mortality.

There is some indication this intervention may have clinical benefit. It was noted that a number of adverse events plausibly related to better early postoperative care (e.g. re-admission rates, MERT calls on the ward, re-operation) may have been less common in the after-period at RAH; however, the small numbers preclude definitive conclusions and these findings should be only seen as hypothesis-generating. Quantitatively, the largest difference was days in hospital due to re-admission, a factor known to be closely associated with in-hospital complications [29]. This highlights the importance of collecting longer-term postoperative outcome data. This is supported by a recent study of the economics of prehabilitation that showed a much greater impact on re-admissions than costs in the primary admission [30]. In addition, a recent study by Bell et al. showed that days at home up to 30 days after surgery is a highly sensitive metric of changes in surgical risk and impact of complications, and has prognostic importance [31].

There are a number of limitations to this trial. First, there were differences in case-mix and circumstances between study sites which, while highlighting the importance of testing and adapting to different sites, limit the validity of pooling of data. Second, the numbers were small in this exploratory study, and with the primary aim being feasibility, recommendations do not support

statistical analysis [19]. However, the fact that a number of secondary endpoints may have been less common in the after-group suggests a trial involving a larger number of patients is worthwhile.

This trial shows that an advanced recovery model of care is feasible at hospitals with sufficient numbers of relevant patients and an adequate pool of staff. A larger trial is indicated now that the profile of outcomes is better understood and the factors affecting feasibility better appreciated. The data in this trial also confirm that even moderate-risk patients may be at high risk of serious adverse events early after surgery, and that delayed events such as re-admission are common. The nature of the events, such as sustained hypotension, respiratory problems and pain management issues, suggest that standard ward-level care may not be adequate for detection and management of these issues. Whilst this is a small trial, the data suggest that extended care into the first postoperative day in the recovery room setting may have clinical benefit and should be explored further to determine the impact of this intervention on the incidence on postoperative outcomes and establish whether it is cost effective.

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Table 1 Characteristics of patients receiving standard ward level care (in the before-periods) and advanced recovery room care (in the after-periods) at each site. Values are median (IQR [range]) or number.

	Royal Adelaide Hospital		The Peter MacCallum Cancer Centre	
	Before n= 71	After n = 55	Before n = 24	After n = 16
Age; y	73 (65–80 [38–93])	74 (68–80 [36–97])	68 (53–79[36–96])	69 (60–75[40–80])
Sex; male	42	29	13	12
Elective surgery	48	31	24	16
ASA physical status 1–2	5	11	6	2
ASA physical status 3–4	66	44	18	14
Predicted 30-day mortality (%)	1.5 (1.3–2.4 [1.0–4.0])	2 (1.4–2.7 [1.0–3.8])	2.1 (1.3–2.6 [1.0–3.4])	2.0 (1.5–2.5 [1.0–3.4])
Duration of surgery; min	136 (63–218 [1–540])	174 (127–248 [37–386])	178 (118–237 [40–608])	240 (180–284 [127–533])
Surgery types				
- General	10	4	8	5
- Orthopaedics	19	17	-	-
- Vascular	14	14	-	-
- Colorectal	7	12	3	2
- Urology	11	1	5	5
- Gynaecology				

- Plastics	3	4	1	1
- Other	3	3	4	3
	4	-	3	-

Table 2 Postoperative events in the before and after periods. Values are number or mean (SD). MERT, medical emergency response team; AARC, advanced recovery room care; ICU, intensive care unit; QoR-15, 15-item quality of recovery score; EQ-5D-5L, five-level version of the EQ-5D.

	Royal Adelaide Hospital		The Peter MacCallum Cancer Centre	
	Before n = 71	After n = 55	Before n = 24	After n = 16
Patients meeting MERT criteria during ARRC	n/a	30	n/a	1
Patients meeting MERT criteria in the ward	23	4	2	5
Unplanned ICU admission from the ward	7	1	-	-
ICU transfer from ARRC	n/a	6	n/a	-
Quality of recovery score ; QoR-15	105 (23)	111 (23)	100 (24)	116 (40)
Quality of life score at 90 days; EQ-5D-5L	8.6 (3.9)	7.9 (3.9)	8.5 (3.8)	7.9 (3.2)
Duration of stay; days	9.2 (8.2)	9.2 (9.6)	7.6 (5.1)	10.9 (7)
Patients re-admitted within 90 days	25	12	6	5
Re-admission duration of stay; days	10.3 (7.5)	5.5 (5.8)	11.2 (11.3)	9.0 (8.4)
Mortality at 90 days	3	6*	-	-
Re-operation within 90 days	7	1	1	1

*Three patients in the after group were treated with palliative care after surgical findings revealed inoperable disease, compared to zero in the before group

Figure Legends

Figure 1. Study flow diagram of patient recruitment at the Royal Adelaide Hospital for the before and after periods. NSQIP, American College of Surgeons National Surgical Quality Improvement Program; ICU, intensive care unit.

Figure 2. Study flow diagram of patient recruitment at the Peter MacCallum Cancer Centre for the before and after periods.

Figure 3. Study flow diagram of patient recruitment at Lismore Base Hospital for the before period only (this site did not complete the after period).

Online supporting information

Figure S1. Advanced recovery room checklist

Figure S2. Current medical emergency response call criteria at the Royal Adelaide Hospital, Adelaide, Australia.

Figure 1
CONSORT diagram from Royal Adelaide Hospital

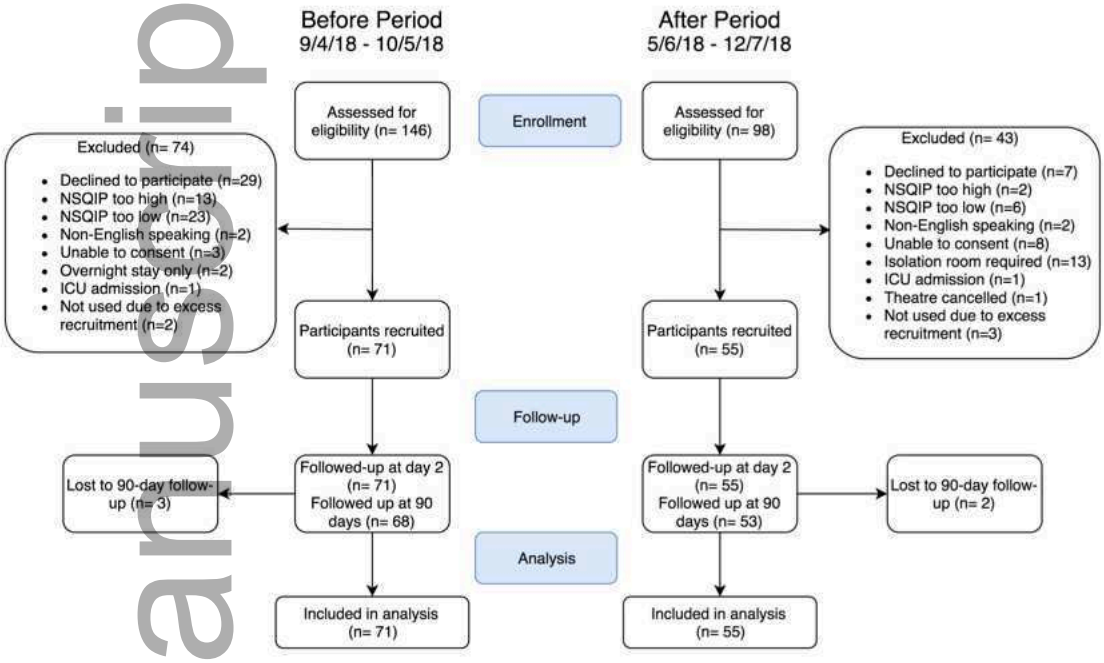

Figure 2
CONSORT diagram from Peter MacCallum Cancer Centre

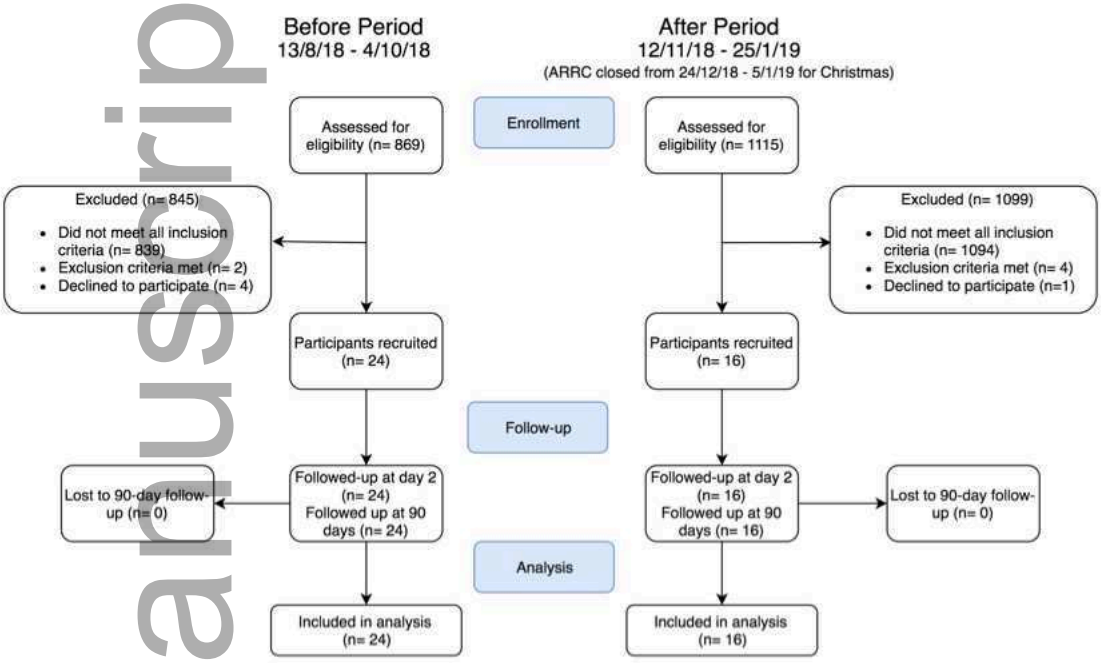

Figure 3
CONSORT diagram from Lismore Base Hospital