JOURNEY TO SOCIAL INCLUSION MARK II: A randomised control trial to assess a modified homelessness intervention (J2SI Mark II)

STUDY PROTOCOL

Professor Paul Flatau[1], Dr Monica Thielking[2], Assoc/Prof Lisa Wood[1,3], Assist/Prof Karen Martin[3,1], Ms Shannen Vallesi[1,3], Dr Ryan Courtney[4], Ms Elizabeth Whittaker[4,1] and Dr Kaylene Zaretzky[1].

1) The University of Western Australia Centre for Social Impact, The UWA Business School, University of Western Australia

2) School of Health Sciences, Swinburne University

3) School of Population Health, University of Western Australia

4) National Drug and Alcohol Research Centre, University of New South Wales

30 November 2015

Research Team

Professor Paul Flatau[1], Dr Monica Thielking[2], Assoc/Prof Lisa Wood[1,3], Assist/Prof Karen Martin[3,1], Ms Shannen Vallesi[1,3], Dr Ryan Courtney[4], Ms Elizabeth Whittaker[4,1] and Dr Kaylene Zaretzky[1].

1) The University of Western Australia Centre for Social Impact, The UWA Business School, University of Western Australia
2) School of Health Sciences, Swinburne University
3) School of Population Health, University of Western Australia
4) National Drug and Alcohol Research Centre, University of New South Wales

In addition to the research team there will be a research two research assistants employed by and located at Sacred Heart Mission who will administer the surveys and collect data. Training will be provided by UWA and Swinburne University.

A PhD student, located at Swinburne University and supervised by Dr Monica Thielking, will also be completing their higher research degree on the J2SI Mark II project. A scholarship has been provided, with support from Sacred Heart Mission, UWA Centre for Social Impact, Swinburne University and the Brain and Psychological Sciences Research Centre (BPsyC).

Enquiries

Any enquiries about or comments should be directed to:

UWA
Professor Paul Flatau
Centre for Social Impact
Business School, University of Western Australia (M261)
35 Stirling Hwy, Crawley, WA 6009
E: paul.flatau@uwa.edu.au
T: (08) 6488 1366

Swinburne University
Dr Monica Thielking
Swinburne University of Technology
Faculty of Health, Arts and Design
Department of Psychological Sciences (Mail H99)
PO Box 218 Hawthorn, Victoria 3122
E: mthielking@swin.edu.au
T: (03) 9214 4402

List of Acronyms

3-ILS	Three Item Loneliness Scale
ADIS	Alcohol and other drug information system
ASSIST	Alcohol, Smoking and Substance Involvement Screening Test
BTQ	Brief Trauma Questionnaire
CMI	Client management system
CSI	Centre for Social Impact
CRIS	Client relationship information system
CRISSP	Client relationship information system for service providers
DASS 21	Depression, Anxiety and Stress Scale (21 questions)
DHS	Department of Human Services
ECIS	Early childhood intervention service
ESSI	ENRICHD Social Support Instrument
HiiP	Housing integrated information platform
ISEL-12	Interpersonal Support Evaluation List
J2SI	Journey to social inclusion
K10	Kessler Psychological Distress Scale
KRW	Key referring worker
ODS	Operational data store
OOHC	Out of home care
OTI	Opioid Treatment Index
PCL-C	PTSD CheckList – Civilian Version
RA	Research Assistants
SDS	Severity of Dependence Scale
SF-36	Short form health survey (36 questions)
SHM	Sacred Heart Mission
SISES	Single-Item Self-Esteem Scale
SITBI	Self-Injurious Thoughts and Behaviors Interview
S-WEMWBS	Short-version Warwick-Edinburgh Mental Wellbeing Scale
TAU	Treatment as usual
UR	Unit record
UWA	University of Western Australia
VAED	Victorian admitted episodes dataset
VEMD	Victorian emergency minimum dataset
WHOQoL-BREF	World Health Organization Quality of Life Bref Questionnaire

Contents

1 Introduction

1.1 Hypothesis

The J2SI Mark II enhanced service model will lead to improved housing, employment, social, and mental health and well-being outcomes for homeless participants when compared to those receiving a standard service.

1.2 Background and Rationale

Homelessness is a significant problem facing approximately 1 in every 204 Australians[1]. People who experience homelessness share many common experiences, but there is also considerable diversity within the homeless population. For example, it is widely recognised that some people have a short experience of homelessness, while others remain homeless for a long period of time. This is crucial as among the long term or chronically homeless population there are higher rates of physical and mental health problems, substance abuse issues and histories of traumatic life experiences. People who are chronically homeless often report that they have few, if any, family or mainstream connections, and while some endure acute isolation, others become deeply mired in the homeless subculture[2]. Existing research undertaken by the research team previously clearly demonstrates the high economic and social costs of chronic homelessness. Reducing the number of people who experience chronic homelessness is now a major policy focus in many Western countries, including Australia[3].

In November 2009, Sacred Heart Mission (SHM) launched a three year pilot of the Journey to Social Inclusion (J2SI) program. J2SI worked with 40 people experiencing long-term, chronic homelessness, delivering a highly intensive model of case management that supported participants across four integrated service delivery elements, working towards a common goal of social inclusion by addressing participants' issues and pathways into homelessness and the dynamics that make it difficult to escape.

The J2SI service model has been designed to provide people who are chronically homeless with skills that reduce their disadvantage and aid in their successful transition out of homelessness and into mainstream life. The J2SI model draws on local and international research that shows chronically homeless individuals benefit from individually tailored, on-going, intensive support and assistance.

The J2SI model is a significant departure from existing approaches which often have strict limits on the amount of time they have available to support people—an approach which has proven to be ineffective with respect to breaking the cycle of chronic homelessness. Integral to the J2SI model is the provision of intensive long term support (three years), small caseloads (a worker to client ratio of 6:1) and the integration of therapeutic and skills building services. Given the uniqueness of the J2SI approach, Sacred Heart Mission, in combination with its funding partners, have committed to a full and rigorous process, impact and economic evaluation of the J2SI model.

The research study as detailed in this protocol will:

a) Track changes in the participants' social and economic participation, their housing stability, their mental and physical wellbeing and also their levels of service usage and examine differences between the treatment group and the control group.
b) Establish the net economic benefits of the model.

Full details of the J2SI intervention model are contained in appendixes to the UWA Human Research Ethics Committee application.

1.3 **Study Aims**

J2SI Mark II is an intervention that aims to break the cycle of chronic long-term homelessness and improve housing outcomes and the health of those experiencing homelessness. A pilot study of the initial program was completed in 2013 examining the effectiveness of the program and demonstrated positive outcomes for participants. However, the program required enhancement and a more rigorous evaluation.

The J2SI Mark II research project aims are to:

1) Evaluate the impact of a new enhanced homelessness intervention compared with existing service provision with regards to outcomes in the following domains:
   - Education, Employment and Income;
   - Social Inclusion;
   - Mental Health;
   - Physical health;
   - Housing;
   - Service Usage.
2) Examine the cost of the new homelessness program compared with existing service provision and assess the cost-effectiveness of the J2SI service Model – Mark II; and,
3) Provide a framework for scaling up the intervention pending positive evaluation findings.

1.4 **Objectives**

1) Investigate the impact of an integrated homelessness prevention intervention on positive mental wellbeing, mental ill health, quality of life and behavioural risk factors at baseline, during and after the study;
2) Identify changes in protective and risk factors for mental health (e.g., social support networks, loneliness) and behavioural risk factors (smoking, alcohol, drug use) at baseline, during and after the intervention;
3) Model the relative and combined contribution of housing support, educational and employment opportunities, access to services and support to the health and wellbeing of participants at baseline, during and after the intervention;
4) Evaluate changes in health outcomes and service usage at baseline, during and after study; and,
5) Model the cost effectiveness of the program in relation to service usage, emergency admissions, and contact with justice services.

1.5 **Outcome Measures**

There are five high-level outcomes that we expect as result of the J2SI intervention. These are:

1) Improved health & wellbeing;
2) Increased social participation;
3) Increased capacity for independence;
4) Economic participation;
5) Sustained housing.

In addition we anticipate being able to evidence system outcomes. These will be measured through the evaluations and include:

1) Greater accountability and performance management of agencies working with homeless people with complex needs;
2) Reduced use of general hospital and psychiatric services in the key locations;
3) Contribution to the reform of the mental health, drug and alcohol and disability services systems to ensure they work more effectively for homeless people with complex needs;

4) Contribution to the reform of the homelessness and housing service system;
5) Development of an improved response to the experience of trauma.

2 Methodology

J2SI Mark II is a three-year, pragmatic, mixed method, multi-site randomised control trial comprising 120 participants (60 J2SI Mark II services, 60 Treatment as Usual (TAU)). The size of the treatment group (J2SI Mark II services) is capped at 60 reflecting funding constraints on the partner organisations delivering the J2SI Mark II program. Sacred Heart Mission and partner organisations do not have the capacity to take more than 60 participants in the program. However, they can support an additional 10 participants in the non-treatment group to account for possible higher sample attrition rates and/or improved post-data collection matching of the intervention and TAU group.

This project will involve the collection of quantitative data (via surveys with study participants at periodic time points) and qualitative data (via in-depth interviews). Additional qualitative data will be collected from staff delivering the intervention program (via interviews and/or focus groups).

An economic evaluation will be undertaken using both self-report data on health service usage and engagement with the justice system and Victorian health data to examine changes in the cost of utilisation of health services as a result of the intervention.

To examine the impact of the intervention on health and justice service outcomes and health and justice costs as well as to gather information on the homelessness service history of the participant, consent will be sought from the participant to obtain their Medicare number and to link their survey responses to Victorian Health and Department of Human Services data bases as well as the Australian Institute of Health and Welfare Specialist Homelessness Collection data. An application for linkage to Victorian administrative data will be lodged with the Victorian Data Linkages Unit vdl@dhhs.vic.gov.au for selected data items from the Victorian Health Department and Department Human Services (DHS) (these two Departments are merging) databases:

a. Housing/public housing tenants database (the HiiP database) (DHS)
b. Hospital Admissions Victorian Admitted Episodes Dataset (VAED) (Victorian Health Dataset)
c. Emergency admissions Victorian Emergency Minimum Dataset (VEMD) (Victorian Health Dataset)
d. Mental Health ODS
e. Alcohol and Drugs ADIS
f. Out of Home Care (for retrospective records of OOHC)
g. CRISSP – CRIS (DHS).

The CRIS (Client Relationship Information System) is the client information and case management system used by Child Protection (includes OOHC), Youth Justice, Disability Services, Early Childhood Intervention Services (ECIS) and the Refugee Minor Program.

CRISSP (Client Relationship Information System for Service Providers) is a free, web-based client information and case management system offered to Community Service Organisations that are funded to provide services in:

- Child Protection Placement and Support
- Disability Services
- Youth Justice
- ECIS
- Family Services

The CMI/ODS (Client Management Interface/Operation data store) records Mental Health service data items collected from each service provider's local client information system. This includes restraints and seclusions as well as business critical VEMD and VAED information.

- Client Management Interface (CMI): the CMI is the local client information system used by each public mental health service
- Operational Data Store (ODS): the ODS manages a set of select data items from each CMI and is used to: allocate a unique (mental health) registration number for each client, known as the statewide unit record (UR) number, share select client-level data between Victorian public area mental health services (AMHS) to support continuity of treatment and care.

The ADIS (Alcohol and Other Drug Information System) collects information on Alcohol and Other Drug treatment service provision.

The HiiP (Housing Integrated Information Platform) Client Management System is a record of all clients who have had a history with the Office of Housing. This may have been through housing applications, bond loans, etc.

The study will utilise administrative data on the resources and costs of intervention delivery as provided by the referring services together with estimates of the 'cost offset' of the intervention (both via linked administrative data and self-report data) and the differential outcomes achieved by the intervention group.

2.1 **Instruments**

The survey for J2SI Mark II will utilise appropriate tools and questions included in the Pilot Survey (2009 – 2012), which combines standardised tools and questions that were specifically developed for this project. The survey instrument will be enhanced in a number of ways particularly in terms of substance use and dependence, harm minimisation, independent living skills, homelessness histories and tenancy outcomes and overall well-being. The same survey instrument will be used for both the intervention and comparison group.

The survey instrument will elicit data in the following areas:

- **Housing -** Homelessness and housing history; Affordability; Mobility/stability/continuity; Location; Quality; Security; Privacy;
- **Education, Employment and Income -** Participation in Education; Current labour force status; Characteristics of current jobs; Employment history; Income (including both labour and non-labour income);
- **General health –** General health (SF-36); Chronic diseases; access to treatment/services;
- **Mental Health -** Depression, anxiety and stress (DASS 21); Psychological Distress (K10); Wellbeing (S-WEMWBS); Diagnosed mental health conditions; Engagement with mental health professions and treatment; Hospitalisation; Other mental health issues; Resilience/empowerment; Self-esteem (SISES); Suicide and self-harm (SITBI);
- **Alcohol and Drug use-** Alcohol, smoking and substance use (ASSIST); harm minimisation (OTI); dependence (SDS);
- **Trauma -** Stressful life events (BTQ); Traumatic stress reactions (PCL-C);
- **Service Usage -** Health services ; Homeless services; Housing services; Contact with justice system; Contact with welfare systems; Contact with employment services; Contact with training services;
- **Social Inclusion -** Relationships and support (ESSI); Identification with the homeless subculture; Leisure and recreation; Independent living skills; Social participation (ISEL-12); loneliness (3-ILS); and,
- **Overall Well-being -** WHOQoL-BREF.

Where possible the survey will use validated tools and items tested in the pilot study. However, some new items are being developed as some standardised tools used are problematic with respect to eliciting meaningful data from people who are chronically homeless. This is so on two counts. First, they have typically been developed for clinical contexts or standardised on domiciled

populations. Second, they are often intrusive and time consuming and tend to be insensitive to the often traumatic life experiences of the participants.

The survey will be administered using an online interface via UWA's Qualtrics program. The survey will be administered by the Sacred Heart Mission Research Officer and Project Officers who will conduct face-to-face interviews with study participants and enter their responses using an iPad. The project team will be providing training (see section 2.2) to the Sacred Heart Mission Research Officer and Project Officers and to workers and managers across the three relevant sites and will be continuously overseeing the process.

2.1.1 Instrument Registration

Once the survey has been finalised we will register the use of: S-WEMWBS with the Warwick Medical School; SF-36 with Medical Outcomes Trust, Health Assessment Lab and QualityMetric and; WHOQoL-BREF with the World Health Organisation.

The study will comply with the CONSORT 2010 checklist when reporting results from the randomised trial.

2.2 Staff Training

Professor Paul Flatau and Dr Monica Thielking will undertake staff-training workshops over a two-day period. The training will be a combination of theory/knowledge acquisition and active/skill-building participation. Main learning outcomes from training include:

- Introduction to homelessness;
- Findings from homelessness research;
- Overview of trauma and trauma in homelessness populations;
- Service integration and client integration – why it matters;
- Establishing trust and rapport;
- The J2SI Mark II Intervention;
- Eligibility;
- Randomisation;
- Research ethics and protocols;
- Researcher and participant safety;
- The J2SI Mark II survey.

Each staff member will receive a manual, which includes all overheads and copies of survey instruments. During the training session, staff will have an opportunity to practice administering the survey, and to make decisions on how to respond to various participant presentations via hypothetical role-play scenarios.

2.3 Participant Recruitment

Posters will be displayed at each of the locations describing the study (Sacred Heart Mission, VincentCare and St Mary's House of Welcome). The poster clearly states that participants will be required to complete 7 surveys over a period of three years and that there is approximately a 50/50 chance of being assigned into the intervention or comparison group. The poster will not state that reimbursement payments are offered to reduce an incentive for participation. Clients will only be informed of reimbursement at the time of consent (i.e., once they have met eligibility criteria).

Every new client that presents at one the partner organisations will be referred to the key referring worker (KRW) who will be responsible for answering questions, completing the referral/eligibility form and setting up the interview time for consent and baseline survey. There will be one KRW at each of the three recruitment sites. In addition, the KRW will screen every person who attends each intake site (in addition to new clients) to ensure every person has been invited to participate, this ensures that no clients are handpicked or excluded. The three KRWs across the three sites will have

extra training on the J2SI process and project. This will ensure that they will be able to provide consistent information to all clients.

If the client meets all eligibility criteria and they provide written consent after they have read the information sheet, and had any questions answered, they will be randomly assigned into either the intervention or comparison group.

2.4 **Participant Selection**

From the 7th December 2015 each person who seeks a service at Sacred Heart Mission, VincentCare and St Marys House of Welcome will be will be assessed for eligibility for inclusion into the study by the key referring worker.

Eligibility assessment and recruitment will be assessed until a total of 120 participants are recruited. (SHM has indicated that if budget allows, another 10 Treatment as Usual participants will be selected into the study at the start of the project to manage attrition during the project and to provide greater flexibility over matching with the treatment group.) New J2SI participants will be enrolled into the project if existing participants disengage in the first six months of the study.

Recruitment will be split over the three sites with 50% of all participants being recruited from Sacred Heart Mission located in St Kilda (60 people in total; 30 intervention, 30 comparison), and 25% each from both VincentCare in North Melbourne (30 people in total; 15 intervention, 15 comparison) and St Marys in Fitzroy (30 people in total; 15 intervention, 15 comparison) [see Figure 1]. Capacity for participant recruitment into this study is constrained by funding.

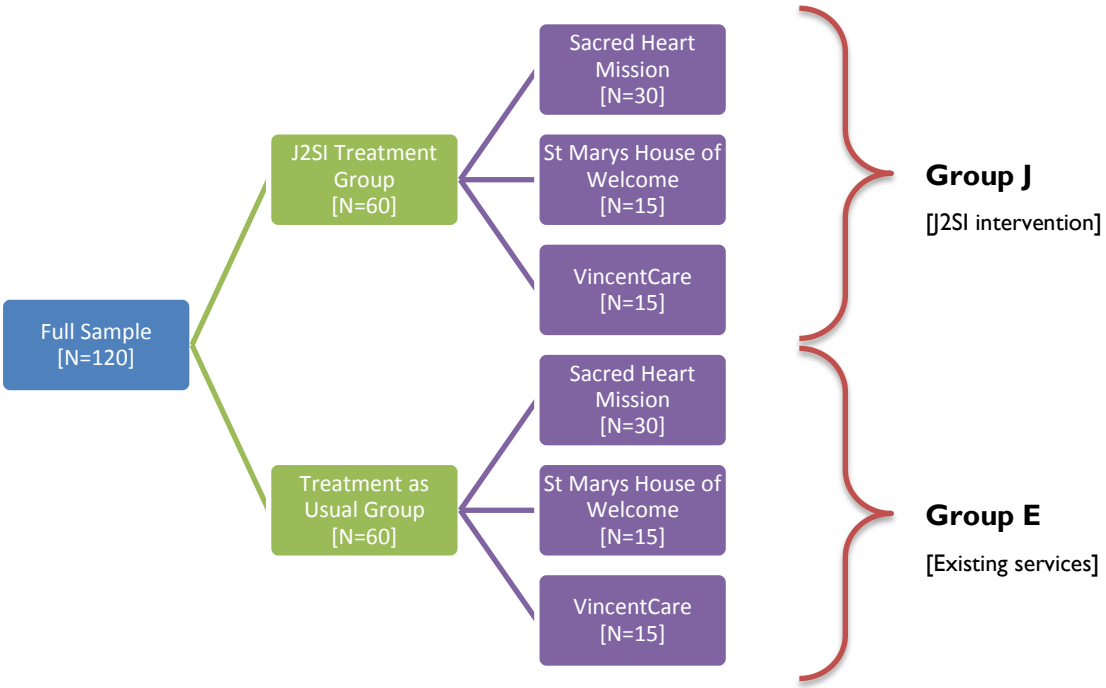


Figure 1: Participant allocation to treatment group from each referring site.

2.4.1 Inclusion Criteria

Eligibility criteria for the study:

- Have been sleeping rough continuously for more than a year OR who are homeless and have experienced several episodes of homelessness over the past three years OR who are currently permanently housed, are at risk of homelessness and have been homeless at some point in the last six months; AND
- Have received some level of case management response from SHM, VincentCare, St Marys House of Welcome OR are well engaged with an on-site Program but have been unable to secure a case management response; AND
- Are aged between 25 – 50 years; AND
- Are a permanent resident; AND
- Are eligible to access public and/or community housing; AND
- Agree to participate in the program.

2.4.2 Exclusion Criteria

Exclusion criteria for the study:

- People who are currently receiving other long term intensive support (e.g., Street2Home); OR
- People experiencing language barriers that require an interpreter service but budget constraints limit the ability to provide interpreter service support; OR
- People experiencing an unmanaged mental illness of a severe nature affecting an ability to provide consent and complete a survey even with a guardian present; OR
- People who for any reason are unable to a) give informed consent or b) participate fully in the intervention or study even with guardian present; OR
- People deemed by agency staff to pose an identifiable safety risk to agency staff, researchers, other people or the participant themselves.

2.5 **Participant Randomisation**

Eligible participants will be randomly assigned in the two groups, Group J and Group E. Group J will receive J2SI services (the treatment group) and Group E will continue to receive existing services (TAU group). Due to funding constraints there are only 60 spaces available Group J and 60 (plus 10 if funding permits) places for Group E. The ten extra participants in Group E (the highest number SHM can provide for in its budget) is to account for the expected higher level of attrition in this group and also to allow for better matching with the treatment group at the analysis point.

Current research on best practice participant selection in RCT studies suggests that participants should be randomly allocated to a treatment or non-treatment group based on a computer generated allocation[4]. This is considered 'gold standard' as it prevents selection bias and ensures against accidental bias, permits chance to determine group allocation outcomes and ensures each participant has a relatively an 'equal chance' of receiving treatment. However, Sacred Heart Mission has provided advice to the research group that use of computer generated allocation in the pilot generated a level of concern on the part of the participants as to whether allocation was in some way 'rigged' to achieve a particular outcome. They have indicated a strong preference that use of non-computer-generated number approach should be used in the randomisation process.

The researchers are aware of confounding variables, that sometimes make simple randomisation a less than ideal selection method for small sample sizes of <60. There is a risk that there may be an imbalance of covariates within a particular group. However, the nature of the current study is to select a representative group of homeless adults that access specialist homeless services. Such

groups often vary on a range of factors such as age, gender, length of homelessness, type of homelessness and type/severity of issues. Therefore, the only one criteria of importance for this study is homelessness (apart from the specific exceptions listed above). We expect all participants to be experiencing homelessness (as defined in our criteria and by the accepted interpretations of homelessness in Australia), and although within group differences may be explored, it is not the primary feature of the analysis and will be affected by power issues. The analysis will study the differences in outcomes of homeless adults who received the treatment compared to those who did not. The two samples, will hopefully and most probably be, what Bottomley described as a "complex whole" [5].

It has been suggested in the literature that where there is a strong relationship between participants and those who are providing interventions, and where selection is based on interview, that the selection process occurs outside of this relationship[6]. In the present context, the sequence to final randomisation will be as follows.

First, information regarding the intervention and the study will be posted in partner organisation centres. Individuals will be asked by centre staff and can independently approach staff at the service centres whether they are interested in being part of the intervention and participating in the study. If they are information will be provided to potential participants. If they agree to be part of the study and sign consent forms then the centre staff will complete an eligibility checklist with potential participants. The results of the eligibility checklist will be assessed by a third experienced independent party who subsequently makes a decision on eligibility. If the participant is deemed eligible then they will complete the baseline survey of the research study with the interview team. Following the baseline interview, the interviewer will complete the randomisation process with the participant.

The sequentially numbered, opaque sealed envelopes method [7] is both a cheap and effective method of randomisation. It is the most accessible and straightforward method of maintaining allocation concealment and does not require the use of specialised technology. To use this method we will need the following items; 145 identical, opaque, letter-sized envelopes; 145 sheets of standardised paper; 145 envelope sized sheets of carbon paper and approximately 70 metres of household aluminium cooking foil.

Step 1:

Cut the aluminium foil into 145 sheets that are of the same width and twice the height of the envelope. Separate the standard-size paper into 3 piles of 60 (treatment), 70 (TAU) and 15 (5 blank envelopes to be prepared per site so that last person allocated is not aware of their position. On the first set of 60 sheets, write Group J and on the second set write Group E.

Step 2:

Select one sheet of standard-size paper marked Group J and fold it to fit in the envelope. Next, place 1 sheet of carbon paper on top of the folded 'group j' allocation paper with the carbon side facing the paper and fold 1 sheet of aluminium foil over both sides of the carbon and paper combination. Place the completed inset into a blank envelope, with the carbon paper closet to the front of the envelope. Complete all 60 of the treatment envelopes and then sign your name, in pen, over the top of the envelope seal.

Step 3:

Repeat step 2 for the 70 TAU envelopes and the 15 blank paper envelopes. Do not mix the piles together and do not write on the envelopes (with the exception of signing your name).

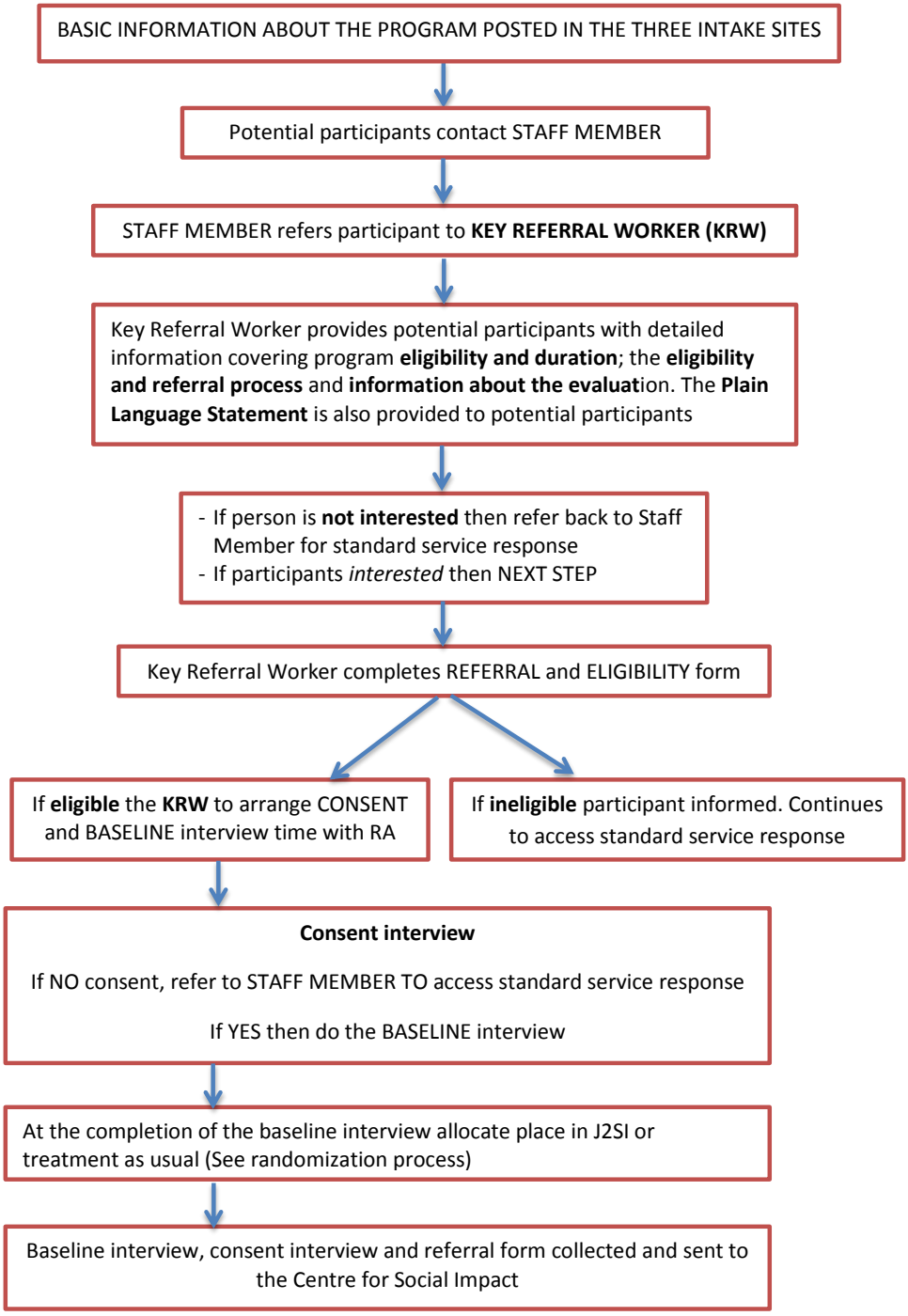
Step 4:

Place 30 treatment and 34 TAU envelopes in one pile (SHM), then 15 treatment and 18 TAU envelopes in a second pile (VincentCare) and the remaining 15 treatment and 18 TAU envelopes in a third pile (St Marys HoW). Shuffle each of these three piles as you would shuffle a deck of cards, once you are satisfied that the envelopes are shuffled add the 5 blank envelopes to the back of each

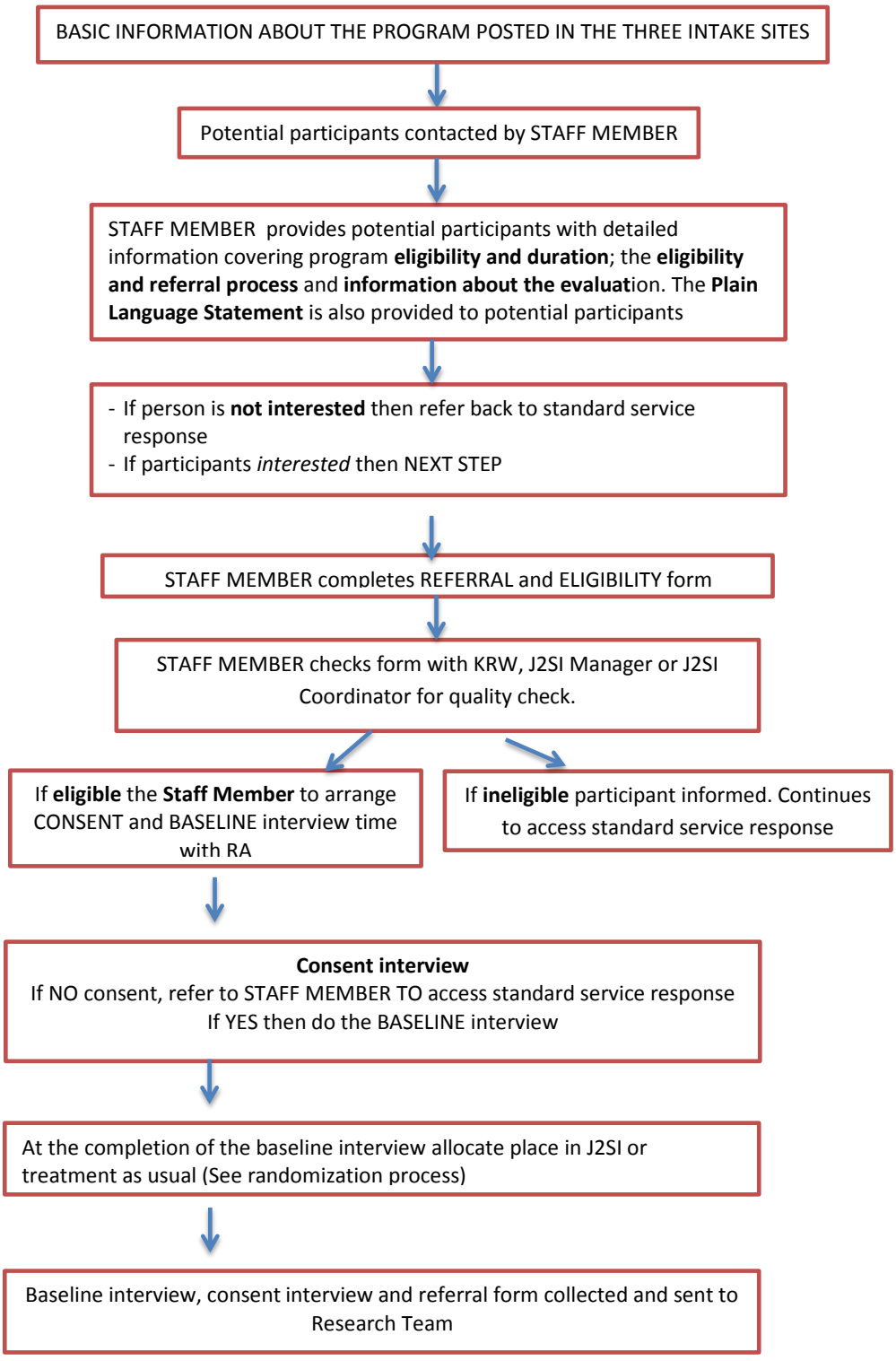
pile and sequentially number each pile of envelopes on the front of the envelope with pen (1 to 69 for SHM; and 1 to 38 for both VincentCare and St Marys). Place the envelopes into three plastic containers in numerical order, ready for use.

The following referral, selection and randomisation pathways will be adopted. The research will be compliant with the CONSORT guidelines and we will follow the CONSORT checklist and report according to the CONSORT flow diagram set out below.

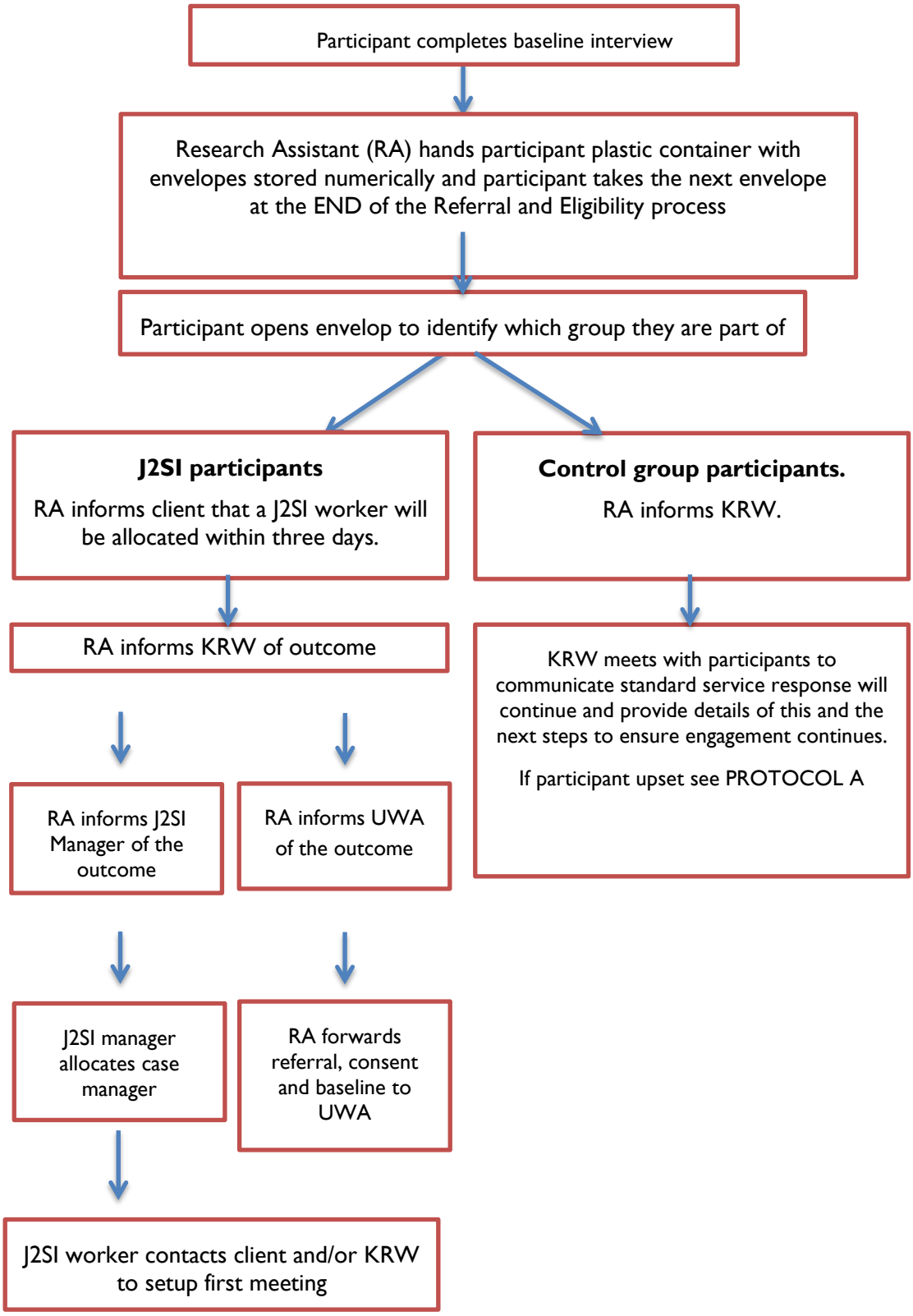
J2SI Referral Pathway I:



J2SI Referral Pathway II

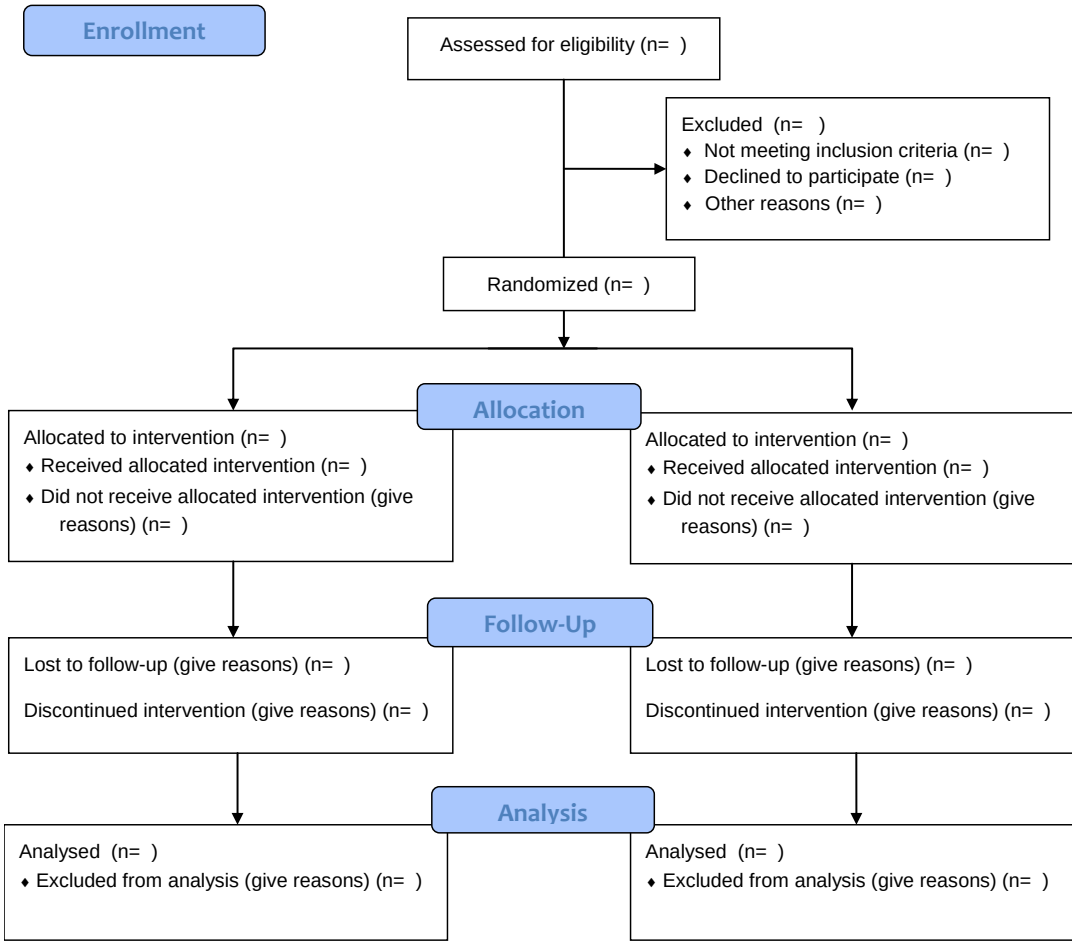


J2SI Mark II randomisation process



UWA – University of Western Australia
RA – Research Assistant
KRW – Key referring worker

CONSORT 2010 Flow Diagram



2.6 Participant Retention

J2SI Mark I was able to achieve an 80.9% (85% treatment, 77.3% non-treatment) retention rate at the 36 month follow up. We believe by applying similar retention strategies we will be able to achieve a retention rate of 80% for Mark II.

Efforts will be made to establish trust and rapport with participants at first contact and to explain the importance of their participation in follow-up interviews. At the time of enrolment, participants are asked to provide contact information not only for themselves but also for friends, relatives, service providers and case workers who are most likely to know the participant's future whereabouts and who may be contacted in order to locate them.

Participants are also asked if they can provide the following consents

- I consent to the research team referring to him or herself by name and to mention that they are from the Journeys to Social Inclusion study when contacting me or my nominated contacts (see Locator Sheet) to obtain information, which will enable the research team to arrange followup interviews.

- I consent to the research team contacting Centrelink to obtain information which will enable the research team to arrange follow-up interviews and I have signed a release of information letter for this purpose.
- I consent to the research team contacting other government or non-government agencies to obtain information which will enable the research team to arrange follow-up interviews and I have signed a release of information letter for this purpose.
- I consent to the research team accessing confidential information about me in government administrative databases for the purposes of this research.
- I agree that research data gathered for this study may be published, provided my name or other identifying information is not used.

It is of utmost importance that every effort is made to keep attrition to a minimum. The research team values the time, effort and personal commitment that participants are contributing to the evaluation. To honour and promote this commitment, participants will be reimbursed at each wave of data collection.

We predict that there will be a higher attrition rate in the non-treatment group, if possible we will try and recruit more than 60 people into this group. However, this will be constrained by the RAs capacity (e.g., time taken to perform surveys). If a respondent leaves after baseline but within 6 months we will recruit a replacement participant.

2.7 **Data Collection**

2.7.1 Longitudinal Survey

Study participants will be asked to complete seven surveys over three years;

- Baseline 1/12/15-14/1/16
- July 2016 (6 months after baseline)
- January 2017 (1 year)
- July 2017 (18 months)
- January 2018 (2 years)
- July 2018 (2.5 years)
- January 2019 (3 years)

2.7.2 Qualitative Interviews

Ten interviews per year with participants from both the intervention and comparison groups will explore explanatory mechanisms and contexts that may pertain to the survey findings. Participants invited to be interviewed will be purposively selected to maximise variability (based on their being in the intervention or comparison group, their service use and location). Where possible, exit interviews will be conducted with participants who withdraw from the project.

Study participants chosen on the basis of 'representing different cases' will be invited to participate in two interviews over three years:

- Baseline
- July 2017 (18 months after baseline)
- January 2019 (3 years after baseline)

All staff involved in the project will be invited to participate in interviews and/or a focus group three times over three years:

- Baseline 1/12/15-14/1/16

- July 2017 (18 months after baseline)
- January 2019 (3 years after baseline)

The in-depth interviews will be facilitated by a member of the project team. Protocols are in place for the interviewer in case of participant distress, substance affected participants, disclosing criminal activities and if there are breaches of researcher safety.

3 Ethical Considerations

Approval for J2SI Mark II is currently under consideration from the Human Research Ethics Committee (HREC) at the University of Western Australia.

In accordance with the *National Statement on Ethical Conduct in Human Research* there are a number of topics we have taken under special consideration whilst designing this study, these include Section 2.1 (Potential harms or risks to participants), Section 4.3 (People in dependent or unequal relationships), Section 4.5 (People with a cognitive impairment, an intellectual disability or a mental illness) and Section 4.6 (potential exposure of illegal activities).

Program delivery will not be compromised or change if participants choose to withdraw from the research component of the program.

As we are using a randomised control trial methodology we need to address certain errors which could impact on the interpretation and generalisability of our results. The main errors associated with health services research are bias, confounding and chance.

3.1 **Bias**

There are two main forms of bias which may occur in this study (a) selection bias and (b) observer/information bias.

Selection bias occurs when the two groups being studied differ systematically in some way. For this study participants will be randomly assigned reducing selection bias.

Observer/information bias occurs when there are systematic differences in the way information is being collected for the groups being studied. For this study a training manual will be developed outlining exact protocols for data collection, with training provided to research assistants collecting data to ensure a streamlined approach.

3.2 **Confounding**

By collecting data that may confound impact of the intervention this project will be able to control for confounding factors.

3.3 **Power**

We have calculated the power of our sample based on the Depression, Anxiety, Stress Scale (DASS) which is a well-known scale we are using in the study. Evidence from studies with similar population groups indicate that in relation to the Depression component of the scale, the difference in the response of matched pairs is normally distributed with standard deviation 8. If the true difference in the mean response of matched pairs is 5, we will need to study a minimum of 22 pairs of subjects to be able to reject the null hypothesis that this response difference is zero with probability (power) 80%. The Type I error probability associated with this test of this null hypothesis is alpha=0.05. If the project study attrition rate is 30% then a minimum recruitment sample of 32 pairs needed. In terms of Anxiety and Stress see below:

DASS Anxiety delta=3.7, sd=6 n=23 in each group

DASS stress delta=4.8, sd=9 n=30 in each group

The sample sizes in the study are around twice n numbers listed above.

4 Data Management

4.1 Data Analysis

Data will be analysed using SPSS and STATA. Analysis will include descriptive statistics, cross-tabs and regression analysis.

4.1.1 Impact Evaluation

The impact of the J2SI project will be estimated by differencing the average outcomes of the intervention and the comparison groups. The J2SI impact will be calculated for each of the 6-month periods to study the effect(s) of J2SI over time. For outcome measures which are additive, total effects in the three year period will be examined.

4.1.2 Cost Effectiveness Analysis

To examine the issue of the cost effectiveness of the intervention we will estimate the cost of providing the J2SI Service Model Mark II relative to the cost of providing standard homelessness support services and compare that cost with the differential outcomes achieved under the two alternatives. The latter will be derived from our impact evaluation.

In order to provide a comprehensive estimate of the cost of homelessness programs; the cost of providing these services are examined at a number of levels. Recurrent funding for these programs is the most frequently published and cited cost element. Information regarding recurrent funding is obtained from both published sources and unpublished data provided by government departments. However, government funding only represents part of the total cost of providing homelessness support. In addition to recurrent funding, many services supplement government funding with additional income from sources such as grants, donations and client rent. Primary data is collected from services delivering specialist homelessness programs to examine the extent to which additional income is used to supplement government funding and the recurrent expenditure per client. When considering services that provide client accommodation as part of a period of support, there is a capital cost element in addition to the recurrent element. The value of capital employed in providing client accommodation is examined, and the opportunity cost of capital employed estimated and added into the recurrent cost of providing support. Finally, we examine issues such as government administration costs of programs and other costs associated with providing support.

As a person's outcomes change as a result of homelessness support, there is the potential for their use of non-homelessness services to also change. In some instances this cost will decrease. For example, studies show that prior to support chronically homeless people frequently access high cost hospital based services, but with supported accommodation this use decreases and instead they access lower cost general practitioner or allied health services. However, there is also potential for service use to increase. For example, where people have previously undiagnosed mental health issues that are affecting their ability to maintain stable accommodation, diagnosis and ongoing assistance to manage these issues may result in an increase in health costs that is required in order for that person to achieve the desired outcome of stable accommodation.

As part of the cost-effectiveness analysis we include the change in government cost arising when the use of non-homelessness services by the program's clients changes as a result of receiving

homelessness support. Both self-report and linked administrative data will be used to examine the impact of the program on health costs.

4.1.3 Survey Data

Our primary analysis will be conducted using an intent-to-treat approach, and therefore include all randomised participants. Baseline characteristics of participants in the two groups will be reported using frequency distributions and descriptive statistics including measures of central tendency and dispersion. An unadjusted Chi-Square test comparing outcomes for each treatment group will be undertaken. Further multivariate regression analyses will examine the effect of adjustment for demographic and other covariates which are known to be strong predictors of outcomes (gender, prior homelessness) or that reflected imbalances at baseline.

4.1.4 Qualitative Data

Data will be transcribed verbatim and data analysis will occur immediately following each interview. Content analysis of the data will be undertaken. The transcript will be read line by line and the frequency and pattern of the use of relevant terms will be identified. To ensure rigorous interpretation of the data, data will be collected from a diverse range of study participants to ensure a varied range of perspectives on the topic. All raw data, methods and analysis decisions will be documented throughout the project. After the completion of the data collection and analysis, sufficient detail will be included in the study report to allow readers to assess the appropriateness of the findings and if they are applicable to other settings. To ensure that all conclusions in the study are dependent upon the subjects and not the researcher, key findings will be presented to the research team for discussion.

4.2 Data Management

The principal investigator Professor Paul Flatau will have full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

All data will be stored in a password protected file at the UWA Centre of Social Impact. Data analysis will occur onsite at UWA CSI and at Swinburne University. All data will be de-identified in the reporting of results.

5 Compliance

The research undertaken for the Journey to Social Inclusion Mark II is compliant with the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee's National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015; and the Australian Government National Health and Medical Research Council Ethical Considerations in Quality Assurance and Evaluation Activities (March, 2014). In particular chapter 3.3: Interventions and Therapies, Including Clinical And Non-Clinical Trials, and Innovations of the National Statement on Ethical Conduct in Human Research is of relevance. The study meets guideline 3.3.3 that: "(a) the research is directed to answering a specific question or questions; (b) there is a scientifically valid hypothesis being tested that offers a realistic possibility that the interventions being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burdens, costs and risks; and (c) the size and profile of the sample to be recruited is adequate to answer the research question" and 3.3.6: "The research methodology should provide a rationale for the selection of participants and a fair method of recruitment".

6 Dissemination of Results and Publications

Findings will be presented in a report for stakeholders and funders. Journal papers and conference papers will be completed throughout the research study. The PhD student will first author 4 peer reviewed papers.

7 References

1. Australian Bureau of Statistics. 2049.0 Census of Population and Housing: Estimating Homelessness. Canberra; 2012. Report No. Available from: http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/EB59F237159F7102CA257AB100170B61/$File/20490_2011.pdf

2. Johnson G, Tseng YP. Journey to Social Inclusion Evaluation Methodology - Randomised Control Trial. 2010.

3. Flatau P, Zaretzky K, Brady M, Haigh Y, Martin R. The Cost-Effectiveness of Homelessness Programs: A First Assessment. Melbourne, Vic: Australian Housing and Urban Research Institute; 2008. Report No.

4. Suresh K. An overview of randomization techniques: an unbiased assessment of outcome in clinical research. Journal of human reproductive sciences. 2011;4(1):8.

5. Bottomley A. To randomise or not to randomise: methodological pitfalls of the RCT design in psychosocial intervention studies. European Journal of Cancer Care. 1997;6(3):222-230.

6. Uman LS, Chambers CT, McGrath PJ, Kisely S, Matthews D, Hayton K. Assessing the quality of randomized controlled trials examining psychological interventions for pediatric procedural pain: recommendations for quality improvement. Journal of pediatric psychology. 2010;35(7):693-703.

7. Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. Journal of critical care. 2005;20(2):187-191.