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Positive Changes Associated With a Recovery-Oriented Mental Health Care Training Intervention in the REFOCUS-PULSAR Specialist Care Cluster Stepped-Wedge Randomised Controlled Trial

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Summary

Background: Recovery-oriented practice recognises people's strengths and recovery potential even in the context of ongoing symptoms. PULSAR adapted the UK-developed REFOCUS recovery-oriented staff intervention for use in Australia. This study aimed to establish whether consumers accessing specialist mental health services where staff had received the REFOCUS-PULSAR intervention reported increased measures of recovery compared to consumers of non-intervention services

Methods: A pragmatic two-step stepped-wedge randomised controlled trial at 18 sites grouped into 14 clusters across Public Mental Health Services (PMHS) and Mental Health Community Support Services (MHCSS). The staff training intervention was refined between step-one and step-two. The primary (stream-one) outcome measure was the Questionnaire about the Process of Recovery (QPR) with cross-sectional data collected across three time-points. Stream-two with two data-collection points, included five outcome measures and five experience measures. This trial is registered with ANZCTR, number ACTRN12614000957695.

Findings: 190 staff were trained, representing half of the available staff pool. A considerable challenge for the implementation included substantial staff turnover (27-47% across the three organisations). Between 2014 and 2017, 942 stream-one consumer participants were recruited over three time-points (T0: 301; T1: 334; T2: 307)) with 273 stream-two participants recruited at time-points related to the intervention delivery (baseline: 140, follow-up: 133). Mixed-effects modelling showed a small but significant overall positive intervention stream-one effect ($p<0{\cdot}05$); mean difference between intervention and control groups at year 1 was 4·2 (95% Confidence interval: 1·1 – 7·2); findings were strongest for PMHS in step-two. Stream-two findings of small effects, typically below the study power threshold, in the majority of measures used favoured the intervention condition.

Interpretation: The REFOCUS-PULSAR intervention showed modest but distinct effectiveness in promoting recovery-oriented practice across sectors.

Funding: Victorian Government Mental Illness Research Fund.

Key words: Recovery, Recovery-oriented practice, Specialist mental health services, Mental Health, Training, Psychiatry, Cluster Randomised Controlled Trial, Pragmatic trial, Health services research, Complex intervention, Questionnaire about the Process of Recovery (QPR).

Research in context

Evidence before the study

Searching PsycINFO, Medline and CINAHL, for articles published in English between 1 January 2007 and 16 January 2018, given the development and evaluation of approaches to implementing recovery-oriented practices is relatively recent. .The search strategy combined Boolean key-term operators of: recovery-oriented practice; community mental health services; implementation; and staff training, then identification of further relevant articles from reference lists of key papers, author searches and citation searches in Google Scholar. This identified 16 relevant studies typically assessing staff outcomes after recovery-oriented training programs. While only REFOCUS had been evaluated using a randomised controlled trial design, these studies generally suggest that recovery-oriented training improved staff knowledge and attitudes towards recovery and improved self-efficacy towards providing recovery-oriented care, with a recurrent theme that the organisational culture of the service setting, and the provision of follow-up coaching appear to be important determinants of implementation success. Apart from the REFOCUS trial published in 2015, no others have reported whether consumer outcomes were improved by these interventions.

Added value of the study

The REFOCUS-PULSAR staff training intervention, adapted for Australian service settings from the REFOCUS package and based on the CHIME (Connectedness, Hope, Identity, Meaning, and Empowerment) conceptual framework of personal recovery, was examined through a stepped-wedge randomised controlled trial with quantitative assessment of effect on consumer-rated experience of recovery. Positive findings for intervention effect in the study provide evidence that the REFOCUS-PULSAR intervention as developed and implemented in this study brought about modest improvements in consumer-rated recovery for people using the involved services. The findings also suggest possible improvements in clinical recovery and experience of service.

Implications of all the available evidence

Training health-care workers to deliver recovery-oriented care using the REFOCUS materials developed over time and adapted to local settings can positively influence the process of personal recovery for consumers.

Introduction

Developing evidence around recovery orientation

The construct of recovery now commonly used in mental health care has roots in consumer perspectives[1] and may be distinguished from other conceptualisations by reference to *personal* rather than *clinical* recovery.[2] Recovery-oriented practice (ROP) involves clinical and other staff facilitating a change process through which individuals who have been diagnosed with mental illness are supported to live a self-directed life and to strive to reach their full potential.[3] Promoting recovery within mental health services is well established in mental health policy internationally[4] and in Australia[5] where this study is set. However, the practice lags behind policy: service-level intervention is required to effectively implement practices through which mental health professionals employ skills, values, attitudes and behaviours that support individuals in their personal recovery (ref). The past decade has seen the development of a number of recovery-oriented training programs, such as REFOCUS and THRIVE in the UK, the Collaborative Recovery Model in Australia and Person-Centred Recovery Planning in the USA. They typically emphasize the use of coaching and person-centred, strengths focused and collaborative processes for supporting service users in their recovery. A reference framework for the work on training interventions may be Kirkpatrick's four levels of learning evaluation : K1. reaction, K2. learning, K3. behaviour and K4. results. The literature is strongest on levels 1 and 2, with few programs having evidence at either level 3 or level 4. Typically work at level 4 has not had the strength of evidential value that goes with RCT methods so there is a need for further evidence at this level. Evidence of the effectiveness of these interventions to promote ROP is required across settings, so that they might be adopted with some confidence by services working towards these policy goals.

From REFOCUS to PULSAR – a developmental trajectory

REFOCUS is a staff training intervention that has been developed and trialled in the UK.[2,6,7] In a developmental process informed by the theory of planned behaviour,[8] working towards changing both what practitioners might do with consumers of mental health services (consumers) and how they might do it,[9] the REFOCUS intervention came to include, as elements of a team-based training intervention for community mental health teams in England, three working practices of 'understanding values and treatment practices', 'working to strengths', and 'supporting goal striving'. So, the REFOCUS intervention was designed to promote recovery through changes in staff and team skills, knowledge, behaviour, values, and relationships with consumers.[2,6]

In a large-scale cluster Randomised Controlled Trial (cRCT), the outcomes of usual care plus REFOCUS were compared with usual care only (control group) in 27 community mental health teams delivering services to adult consumers with psychotic disorders. In the primary analyses, personal recovery assessed using the consumer-rated Questionnaire about the Process of Recovery (QPR)[10] did not differ between the REFOCUS intervention group and controls. While secondary analyses suggested that higher team participation was associated with higher staff-reported recovery-promoting behaviour and improved QPR, possible reasons advanced for the negative primary analyses that might be modifiable in subsequent work included the following issues:[7]

1. The REFOCUS recruitment protocol and criteria meant that, on average, consumer participants had been using mental health services for over 15 years, suggesting the possibility of entrenched ways of relating to services and problems that may take longer than one year to change.
2. Participant attrition was higher than anticipated in this 12-month longitudinal study (26% vs 7%) resulting in a reduction in planned statistical power.
3. Inclusion of adaptive design principles{Taylor, 2014 #23} might be advantageous.
4. Future designs might either use a homogenous team-type or stratification by team characteristics.
5. Transition to ROP might require organisation-wide rather than team-level strategies.

The 'Principles Unite Local Services Assisting Recovery' (PULSAR) work program was based in Victoria, Australia. The REFOCUS team advised on project development enabling PULSAR, four years behind REFOCUS in development and implementation, to benefit from lessons learned during REFOCUS. Changes to the intervention included adjustments to the REFOCUS materials to enhance relevance to the local setting and to incorporate developments made in the course of the REFOCUS work after the REFOCUS manual[11] was concluded for REFOCUS study use. The intervention here is referred to as "REFOCUS-PULSAR" (shortened to "PULSAR" in the protocol paper and local implementation[12]) since while it was developed for the PULSAR study,[12] it was heavily based on REFOCUS materials.

The research approach,[12] chosen based on addressing issues 1-5 above, is outlined here with that context as background to the methods section. It involved adoption of a specific cRCT variant involving Stepped-Wedge intervention allocation (a cRCT-SW) where all study sites receive the intervention but time of intervention is allocated randomly, here according to two 'steps', step-one and step-two. Since those people who may benefit most from ROP in relation to personal recovery may be discharged more quickly from treating services than those who do not because of related challenges in clinical recovery, sampling based on people with long-term tenure with those services

may bias against positive findings as noted in point 1 above. Hence, the PULSAR design incorporated three streams. In stream one, rather than following individuals longitudinally through the three years of the study period, a different sample were recruited at each time-point (baseline: T0; year 1: T1; year 2: T2). It is necessary then to maintain tight control on consistency of recruitment processes so that any sampling bias is minimised as a source of systematic error in findings related to intervention effect across time-points. The cRCT-SW research design with repeated cross-sectional recruitment, then, carried possible advantages for point 1-2 above. The 2-year two-step stratified cRCT-SW approach promised greater possibility for progressive refinement of the training intervention through experience, providing some response to point 3. Randomisation in this study was stratified by team type addressing point 4 above. The design also went a small way to address point 5 above since in the later stage of the stepped-wedge design the implementation was in effect organisation-wide across community services.

Streams Two and Three of the PULSAR work program also included face-to-face interviews in two smaller parallel studies, one cross-sectional and the other longitudinal, each with different samples[12],. Implementation of stream-three was unsuccessful inasmuch as recruitment fell substantially short of power targets so that stream will not be reported here. This paper then, is based on findings from streams one and two where power targets were attained. The primary outcome measure collected across all time-points, identified as primary outcome in the protocol paper[12] and on which the study stream-one power calculations were based, was the QPR.

Aims and hypotheses

The aim of this pragmatic cluster stepped-wedge randomised controlled trial was to evaluate the effectiveness of the REFOCUS-PULSAR staff ROP training intervention for improving the experience of personal recovery as reported by consumers using repeated cross-sectional samples. The primary hypothesis was that consumers in the REFOCUS-PULSAR post-intervention clusters would experience significantly greater personal recovery compared to consumers accessing other mental health services that at relevant time-points within the cRCT-SW had not received the intervention. We also investigated change in, clinical recovery and experience of the services.

Methods

Setting and study design

Participating services were involved with providing mental health care to over one million people living in the catchment area of a large Public Mental Health Service (PMHS) in Victoria, Australia.

The catchment area ranges from a relatively affluent coastal city area to the most socio-economically disadvantaged and culturally diverse area in metropolitan Melbourne and includes a semi-rural growth-corridor. In Victoria, state-run public sector specialist clinical mental health services, typically accessed by people with more severe mental illnesses, are block-funded. Specialist mental health services include area-based clinical services comprising a range of teams and service types, including inpatient units, community-based residential rehabilitation, continuing care, and community treatment teams. Residential care, whether acute or longer-term, is typically provided in units of around 25 beds. Caseloads in community services vary from around 10 in Mobile Support and Treatment Services (MSTS) to 25-35 in many community clinics while typical length of care with a particular team may vary between a few days as in Crisis Assessment and Treatment Teams (CATTS) to several years as in MSTS and Community Care Units (CCUs). Mental health care funded by the Victorian government includes substantial investment in the Mental Health Community Support Services (MHCSS), run by non-government organisations, which provide residential and outreach psychosocial support. Government-funded provision of care to the population in need of mental health care for serious mental illness is thus provided by a combination of PMHS and MHCCS.

Within this setting, the temporal context for the work through 2014-2016 included what in organisational terms could be framed as 'Critical Incidents' worthy of some comment:

- The funding environment for public health services in Victoria under the Liberal administration 2010 to 2015 received significant criticism as negative.[13] While the Labor administration that followed has been better reviewed for its support of healthcare,[14] there was limited time for the actions of this new administration to flow through into changes in work context during the project timespan. As well as the general problem of under resourcing, three intersecting areas of change impacted on this project and the research undertaken with specialist mental health services:
    - Long et al (2018) describe, in reporting on a contemporaneous project, how the PMHS "underwent a major restructuring after a significant number of senior staff left the service" (p.2).
    - In 2014 the Victorian State Government introduced a new Mental Health Act,[15] replacing the 1986 Act; but only limited training was offered in preparation for the significant changes in practice required for compliance. The immediate impact of the legislative changes was to produce an uncertain legal environment in which the voluntary PULSAR training modules competed with compulsory MHA training for staff time and attention. Also this compulsory training tended not to focus on the relevant recovery and supported

decision making reforms but rather on the changes to compulsory admission criteria and treatment orders, restrictive interventions and ECT.

- In 2015 the Victorian State Government introduced major reforms of MHCSS which presented substantial challenges for MHCSS organisations involved in this study.[16] This also was an element of the preparation for transition to an individualised funding model under the new National Disability Insurance Scheme, a transition commonly referred to as the biggest change in health services funding in Australia since its current National Health Insurance scheme (Medicare) was introduced in 1984.[17]

Some summary data gives an indication of the trends in activity through time across the PMHS, based on regularly collected data and available reports which are not available in as standardised a way for the MHCSS. The last day of the year snapshot of all PMHS case managed clients rose from 2349 in 2014 to 2462 in 2016, an increment of 5%. By way of indicators on demand factors for the whole service, emergency department presentations increased from 8803 in 2014 to 10004 in 2016 (+14%) and inpatient length of stay decreased on average from 12.8 days to 11.3 days (-4%) as total in-patient separations increased from 3102 to 3633 (+17%). Average length of stay in community services from opening to closing of administrative cases increased by 31% (2014: 157 days, 2015: 170 days, 2016: 205 days).

Within this setting, the main project in specialist care involved three separate studies or streams each with different designs, sampling strategies and measures. Stream one had a cross-sectional complete step-wedge cRCT design with only QPR and demographic data collected from consumers via a mail-out. Stream two had a cross-sectional pre- and post- intervention incomplete step-wedge cRCT design with data collected via face-to-face interviews from a subset of consumers recruited from the Stream one participant pool. Stream three had a longitudinal pre- and post-intervention incomplete step-wedge cRCT design with data collected via face-to-face interviews with consumers from Stream two who had a diagnosis of a psychotic disorder. Stream 3 did not achieve adequate recruitment targets and is not reported here.

Participants

Three organisations that operated in the catchment were involved in the study including the major PHMS and two organisations from the MHCSS sector. These were allthe main state-funded providers of specialist adult mental health services to the catchment area of the PMHS. Specialist care sites or teams within these organisations were identified by the PMHS and MHCSS service partners and all of these were approached and agreed to participate. Staff within these teams were

eligible to receive the PULSAR training intervention if they: (a) were working on a part-time or full-time basis within the team in a direct service capacity (and not employed on a casual basis); (b) had an active case load with consumers who are recruited into the evaluation. Staff were ineligible if they were also working in a non-intervention cluster at the time of training (to reduce risk of contamination). Staff within these teams were eligible to receive the PULSAR training intervention if they: (a) were working on a part-time or full-time basis within the team in a direct service capacity (and not employed on a casual basis); (b) had an active case load with consumers who are recruited into the evaluation. Staff were ineligible if they were also working in a non-intervention cluster at the time of training (to reduce risk of contamination).

Consumers were eligible for recruitment for Stream 1 if they were: receiving care from a participating cluster with contact in the three months prior to data collection; aged 18-75; able to provide informed consent; and proficient in English. People in prison were excluded. Eligibility was established via a screening process conducted by administration and clinical staff at the participating organisations using detailed instructions provided by the research team. A letter sent to all eligible consumers from each cluster site invited completion and return of a survey form comprising demographic information and the QPR. An AUD$10 shopping voucher was sent to participants for returned surveys where contact details were provided. A range of complementary recruitment strategies to promote consumer response to the mailouts were added according to site need.[12] Strategies included, for example, having researchers, including consumer researchers, speak about PULSAR at participating sites; use of publicity materials such as posters or PULSAR-branded materials; and direct contact with clinicians and consumers at participating sites. Through an active quality assurance process monitoring recruitment, and because this was important to the design, the balance of recruitment between onsite recruitment and mailout approaches was kept as consistent as possible across time points and clusters. Decisions on whether or not to repeat bulk mailouts for given clusters or continue onsite recruitment were based on a weekly review of QPR numbers by recruitment method by cluster and taking into consideration the need to also recruit sufficient numbers for face-to-face interviews. Time spent recruiting at T1 and T2 at a given cluster was matched to T0 activity at the same cluster and only adjusted if necessary to match the number of QPRs collected via this method.

Consumers were eligible for Stream 2 and recruited by phone, email or letter if they had provided contact details, consent to be contacted for this purpose and were at the pre or post-phase of an active intervention site at the time of recruitment.

Randomisation and masking

Eighteen mental health care delivery teams, grouped into 14 clusters to enable adequate recruitment in the context of some smaller teams, were classified into seven strata. In the context of substantial variations in the nature and intensity of care typically delivered through the different teams, the strata groupings included teams that were relatively homogenous regarding the specifications of their care delivery. Within PMHS these were: CATTS (x3 teams; two smaller teams grouped into one cluster) and MSTS (x2 teams); CCUs (x2; grouped with MSTS, being smaller teams and introduced earlier as having shared focus on long term intensive work with people with more complex needs); Community Mental Health Services/Continuing Care Teams (x4). The remaining stratum included services delivered by two participating MHCSS, here designated MHCSS-1 and MHCSS-2. These were: Prevention and Recovery Care services (PARCs; x4) delivering short-term, subacute, residential recovery-oriented care; and Community Outreach Services (x3; two from the one organisation grouped into one cluster).

Stratified randomisation was used to allocate clusters to receive the intervention in either step-one or step-two using an online Research Randomiser with randomisation keys corresponding to the seven strata and allocation of clusters within strata to step-one or step-two in the cRCT-SW design. Randomisation was performed offsite by an independent researcher during the third quarter of 2014. As the intervention involves training, specialist mental health care staff were aware of their allocated condition. Consumer participants, however, were not informed if staff at their service received the training and efforts were made to maintain the blindness of research assistants for onsite recruitment. Further details are in the protocol paper.[12]

Procedures

The REFOCUS intervention[2,11] introduced earlier was developed in the UK to promote ROP with a basic structure including recovery-promoting relationships and three working practices listed above. The essence of the REFOCUS intervention is described in a freely available manual.[11] The REFOCUS-PULSAR intervention comprises a manual adapted from REFOCUS, a structured training intervention to support use of the REFOCUS-PULSAR manual, and follow-up sessions called PULSAR Active Learning Sessions (PALS).

REFOCUS-PULSAR development, following Medical Research Council Guidelines for Complex Interventions,[18] and the plan-do-study-act (PDSA) model as a method for controlling and improving process[19] was guided by discussions with the REFOCUS research team, consideration by a Lived Experience Advisory Panel (LEAP), and information from qualitative analysis of group sessions with staff from participating organisations. The content of the REFOCUS manual was substantially retained in the REFOCUS-PULSAR manual[20] with some amendments to contextualise it for the PULSAR study setting including legal and policy contexts. Additions - being less than 25% of the manual - included material related to relapse-signatures and relapse-drills, and material on the CHIME ROP conceptual framework 'Connectedness, Hope, Identity, Meaning, and Empowerment'[6] which was developed during the course of the REFOCUS study. In summary, the REFOCUS-PULSAR intervention was grounded in experience and learning from REFOCUS, research evidence, government policy and law.

The REFOCUS-PULSAR training was supported by a PowerPoint presentation, a manual, session plans and videos. In a change from the REFOCUS intervention, the training was co-facilitated throughout by professional staff, including REFOCUS-PULSAR investigators and staff with lived experience of mental health problems,including the project's consumer researcher which, based on local consultations, was expected to enhance the recovery-orientation of the training. Carer input was included in specific sessions.

The first intervention round for clinical services was developed as a two-day session, with the community services training planned as a separate two-day session in the same week. In addition to two consumer trainers employed by the project, trainers were sourced from clinical services for the clinical sessions and the community sector for the community sessions. This was anticipated as enabling the inclusion of specialist skills and experience in the delivery of training.

Training in the second round was subject to further modifications based on analyses of evaluations of the first round of training by both participants and trainers. The delivery of the intervention was modified to account for previously unknown restrictions on the ability of services to release staff for two days of training. Based on feedback from services, it was identified that attending two days of training for some teams was difficult. This was either due to the workload of the teams (specifically CAT teams) or the recent undertaking of organisational wide recovery training (Ermha). In response to this the training was re-designed so that all material is covered in the first day of training, with more in-depth exploration and practice of the knowledge and skill on day two.

Other modifications were as follows:

Training was restructured to allow half of the two days of training to be combined between the MHCSS sector and MH Staff. Feedback highlighted how the lived experience person or consumer's role in leading training could be experienced as very challenging for some participants particularly if the consumer was experienced as critical of staff. Of course, being open to hearing criticisms from consumers about mental health care is an essential part of any transition to recovery-oriented practice so the training team worked very hard at considering this feedback in subsequent rounds. A key learning was that the introduction of the REACH coaching process needed to be deeply experiential. In particular, the training team formed the view that a crucial element of the delivery was that the lived experience and clinician co-trainers needed to embody the coaching principles in a fully authentic way. In alignment with a PDSA approach we took this on board as much as we could and adjusted the interactive style of the trainers for the second round.

In both steps of training participants were provided with presentation content and other materials giving details on the approach. In the first step, the PULSAR manual was provided in PALS sessions as soon as possible after the training and treated as a workbook to support the PALS session activities. In the second step training, in response to feedback, the manual was provided in the training sessions and referenced regularly during the training. Between steps the PULSAR manual was updated to a second edition. Changes included the addition of sections providing information on Advance statements, Nominated persons and Risk and Recovery and the reference list was expanded. Additional material was also provided in Appendix 2 and the title changed from "Additional resources for understanding values" to "Additional resources for consumers' experiences". Extra web resources were added to Appendix 7 and the title changed from "Example of a relapse symptoms checklist" to "Care plans, and example of a relapse symptom checklist and other resources".

PALS, offered monthly as hour-long sessions to staff and managers of involved teams to support practice-based implementation of ROP, were facilitated by PULSAR investigators and local trainers.

The control condition, standard treatment as delivered through the range of teams introduced above, was governed by national standards,[21] adherence to which is maintained by regular accreditation. Consumers of the service often will have their locus of care change in response to changing needs between the more intensive community teams (CATTS, MSTS), residential options including the PARCs, or less intensive community options. Case management in community clinics often functions to coordinate transitions through these levels of care and seeks to ensure that needs for medication, monitoring, supportive, and psychosocial interventions are met. Teams typically have

multidisciplinary representation from mental health care disciplines with nursing as the largest single workforce component.

At the commencement of the trial the forms of possible adverse events we anticipated included: 1) risk of distress by a participant during an interview; 2) issues related to disclosure of potential self-harm or harm to others 3) risk of harm to staff. We developed an ethics protocol outlining the prevention and management of these risks which was approved by the governing HREC. Participants were also provided with written contact details for complaints, which was the manager of the governing HREC. Beyond the complaints process, we did not systematically collect any other adverse event information from consumers (such as deaths, hospitalisations etc) because the intervention was a training intervention for staff rather than a clinical intervention for consumers so attribution of adverse events from clinical care in the context of the study, of which care guided by PULSAR-REFOCUS principles was but a part, would not have been clear. Further details about adverse events and complaints procedures are provided in Appendix,..

Outcomes

The primary outcome measure collected via the Stream 1 cross-sectional survey (see Table 4, protocol paper[12]) was the QPR, a 22-item consumer-rated Patient Rated Outcome Measure (PROM)questionnaire used to assess experience of personal recovery with each item being rated on a 5-point Likert scale ranging from 0 (disagree strongly) to 4 (agree strongly) and higher score indicating increased recovery.[10] Exploratory factor analysis by the QPR developers suggesting a two-factor structure has not been supported by later studies while a one-factor 15-item scale suggested as a briefer and perhaps more robust alternative has not been independently validated other than within the 22 item questionnaire.[22,23] In this study, Cronbach's alpha was 0·95 for both versions. Since we collected the 22 item version and powered the study based on known properties of this, we retain consistency with our protocol paper and focus on the full-scale 22 item score.

There were two secondary consumer-rated outcome measures collected via Stream 2. The 27-item Importance of services in recovery questionnaire (INSPIRE) is a Patient Rated Experience Measure (PREM) that assesses recovery support from a worker.{Williams, 2015 #30} The two sub-scales of INSPIRE are: Supporting personally defined recovery (Support sub-scale; 20 items) and Working relationships (Relationship sub-scale; 7 items). The measure is scored by converting the mean of all

Likert ratings to a percentage ranging from 0 (low support) to 100. {Williams, 2015 #30} The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) is a 14-item PROM scale designed to assess functional and emotional well-being.{Tennant, 2007 #28} The scale is rated on a 5-point Likert scale ranging from 1 (None of the time) to 5 (All of the time), providing a total score ranging from 14 to 70. A higher score indicates a higher level of mental well-being.

Participant demographics were collected using the *Participant Demographic Record.* Table 5 lists the demographic variables for stream 2. Response categories for the ethnicity variable were chosen to represent the most common cultural/ethnic groups residing in the Monash Health catchment, sourced from the relevant local government websites. An abbreviated demographic record was included in stream 1 and included sex, age, country of birth, year of arrival if born overseas, ethnicity, main language, and length of time the consumer had used mental health services at their current service site.

Additional measures administered to consumers in streams 2 (grouped as PROMS and PREMS) and reported here include:

PROMS

- *The Global Assessment of Functioning Scale (GAF).* The GAF is a researcher-rated measure of an individual's level of social, occupational and psychological functioning. The scale ranges from 0 to 100 with a lower score indicating a lower level of functioning [42].
- *The Social and Occupational Functioning Assessment Scale (SOFAS).* This researcher-rated measure provides an indication of an individual's level of functioning that is not directly influenced by the severity of a psychological condition and includes impairments caused by both physical and mental health conditions. The scale ranges from 0 to 100 with a lower score indicating a lower level of functioning [42, 43].
- *Days out of role.* This item assesses the impact of mental health problems on normal daily activities over the last 30 days.

PREMS

- *The Perceived Need for Care Questionnaire (PNCQ).* This measure classifies the consumers' perception of their need for care according to four levels: no need, unmet need, partially met

need and met need. The PNCQ enables systematic assessment of perceptions of service delivery, especially in relation to mental health service evaluation [38].

- *Client Satisfaction Questionnaire (CSQ).* This consumer-rated measure assesses client satisfaction with the mental health services provided [39].
- *The Mind Australia Satisfaction Survey (MASS).* The MASS is a consumer-rated measure developed by Mind Australia to evaluate overall satisfaction with services provided, individual outcomes associated with service use, and the effectiveness of staff-consumer partnerships in mental health care service delivery [40].
- *The Coercion Ladder.* This visual analogue ladder scale provides a measure of consumers' perception of coercion in their mental health service interactions including both a hospital and community services version [41].

In stream 1 of the cRCT, cross-sectional data were collected from mail-outs to consumers at the three time points; consent was given by return of the completed survey. In stream 2 data were collected in structured face-to-face interviews from a subset of eligible stream 1 consumers who agreed to complete an interview. Participants who completed a face-to-face interview were required to provide full written informed consent for both the interview and to the researchers accessing routinely collected data. Study interviews took around 60-90 minutes. Baseline (T0) data collection occurred in the year prior to and three months after the step 1 intervention was delivered. The first three months after intervention delivery is a period still considered relevant for baseline data collection based on the Kirkpatrick training evaluation model [53] which considers that the embedding of practice change requires a minimum of 9 months after intervention is delivered, including 3 months for consolidation and 6 months for implementation. During both T1 and T2 periods, data collection at individual clusters occurred at a minimum of 9 months after the intervention was delivered to ensure embedding of intervention practices and principles.

In relation to implementation, at the conclusion of their REFOCUS-PULSAR training, staff completed a training evaluation form (Kirkpatrick level 1 (ref)) which included satisfaction ratings from 1 "extremely dissatisfied" to 10 "extremely satisfied"). To measure dosage, team managers or

administrators were asked to record staff movements every three months.{Shawyer, 2017 #12} The percentage of the team that attended at least one training sessions, in both headcount and full-time equivalent (FTE), was calculated for the time of training. Staff turnover was calculated as the percentage of staff who left, joined, or moved internally in the organisation but out of the cluster calculated on headcount. Staff turnover is reported at the organisation level, including data from all teams in each organisation calculated on headcount. Staff who moved into the cluster after training and out of the cluster prior to end of the study are factored into this calculation.

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Sample size

Primary QPR analysis required recruitment of 252 separately-sampled consumers at each of T0, T1 and T2, from 14 clusters (see Table 1) with 18 from each cluster and intervention in step-one clusters between T0 and T1 and step-two clusters between T1 and T2, to detect a medium effect-size representing a change in mean score by 6·34.[12] Sample size calculations were based on an intra-cluster correlation coefficient (ICC) of 0·05; significance level 0·05; power 0·80; and published data about distribution properties of the QPR: mean = 46 ±16. Calculations were done using Stata stepped-wedge V.11.[24] Secondary analyses required a total sample size of 252 consumers over the study period. This was determined to be sufficient to detect medium effect sizes in the QPR and the two secondary outcome measures (WEMWBS and INSPIRE).

Statistical analysis

The stream 1 and stream 2 studies were both designed to detect medium effects in the primary outcome (QPR). Stream 1 was the complete stepped wedge cRCT designed to detect a change in mean QPR score by 6·34, and requiring 756 surveys (252 in each wave, i.e 18 per cluster per wave). Stream 2 was the incomplete stepped wedge cRCT designed to detect a change in mean QPR score by 7.68, and requiring 252 surveys (63 at baseline, 126 at step 1 and 63 at step 2, i.e. 9 per relevant cluster per wave). The secondary outcomes (collected in steam 2 only) were WEMWBS and INSPIRE scores, and both were anticipated to detect medium effects given the overall sample size of 252 (i.e. mean changes in WEMWBS of 4.8 and INSPIRE of 7.72). All sample size calculations were based on 14 clusters; an intra-cluster correlation coefficient (ICC) of 0·05; significance level 0·05; power 0·80; and published standard deviations. All sample size calculations were done using Stata stepped-wedge V.11 (ref).

We did an intention-to-treat analysis in line with a prespecified analysis plan for all outcomes, using Stata (version 15). All patients were analysed in the groups to which their participating clusters were allocated. We analysed all outcomes using multi-level regression models (using linear or Poisson regression, as appropriate), which included timepoint and intervention status as fixed effects, and clusters as a random effect. Timepoint was included as a categorical variable. Covariates were selected based on statistical and clinical considerations, and were age group, gender, sector (PMHS and MHCSS) and step group (in stream 1 models only). No other covariates have yet been investigated for inclusion into the models, and a later separate investigation will explore the large pool of covariates and their effects on the study outcomes. Covariates of age group and gender were included because these are well known to influence clinical outcomes. Sector (PMHS and MHCSS) was included as the most important stratification variable (another 7 strata were necessarily included in the randomisation process to balance team types in test/control groups, as mental health services largely vary in structure/type. But these 7 strata are not used in the modelling as it would produce an overfitted model). Finally, in stream 1 models only, step group was investigated as it denoted if a cluster received the intervention in either step 1 or a year later in step 2 (an important factor as there were temporal changes related to cluster organisation challenges already discussed, and the intervention also was refined and adapted after the step 1 rollout). Furthermore, step group could not be included in the stream 2 models due to its collinearity with intervention status in the incomplete SW design.

As explained in the study protocol paper, it was anticipated that consumers would be modelled as random to account for repeated measures, but it was found that streams 1 and 2 repeated cross-sectional trials (not longitudinal) attracted a high number of singletons (people contributing to one timepoint only), which required an adjustment to the analysis plan. Consumers would be specified as random only if less than 70% of the overall data came from singletons plus over 50 consumers contributed data, defined as such because simulation studies found low levels of bias for models with up to 70% singletons and 50 to 500 clustering units (refs).

Intervention effects are estimated from the models described above, recommended by Hussey and Hughes (2007) (ref). Also investigated (see appendix), and supplied as supplementary analyses are interaction effects between timepoint and intervention status, in which trends across the defined sector (PMHS and MHCSS) are reported (ref).

Role of funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit it for publication.

Ethics approval

Approval was obtained from Monash Health (14102B) and Monash University (CF14/1600 – 2014000773) Human Research Ethics Committees.

Results

Implementation

Step-one Core REFOCUS-PULSAR ROP training was delivered to 84 staff from the three services in the first quarter of 2015, in 22 days of workshops delivered by 7 trainers. Step-two training was held in June-July (plus an extra session in October) 2016 and delivered to 106 staff over 21 days by 8 trainers. In total 190 staff (111 PMHS; 79 MHCSS) were trained. Staff trained included representatives of multiple disciplines but the team-based training approach in the most part did not succeed in engaging senior medical staff – it became apparent through the project that they more typically attend service-wide profession-specific trainings which would not readily be compatible with the cluster RCT model. A medical-specific training of 2 x 1.5 hour sessions was attended by 11 registrars but not by any consultants.

On average across clusters, 49.1% (PMHS: 38.2%; MHCSS: 63.8%) of staff employed at the time of training attended at least one training session. When adjusted for FTE, this percentage was 51.2% (PMHS: 38.8%; MHCSS: 62.4%). Staff turnover was 42.2% for PMHS, 46.7% for MHCSS-1 and 26.7% for MHCSS-2. Positively judged satisfaction (K1) improved significantly from Year 1 to Year 2, Odds Ratio 2·71 (95% CI: 1·04, 7·05, $p = 0·04$). In MHCSS settings PALS came to be integrated into monthly staff support sessions and so the element of this that was PALS-specific cannot be quantified. In PMHS they remained separately conducted. For two PMHS teams despite best efforts scheduling of the PALS did not happen. For 22% of sessions, arranging team sessions was not successful so meetings were with individual clinicians. For all PMHS teams where they did occur (7 team settings including some that were combined), the mean total number of sessions was 8.1, SD 4.7.

Between 18 September 2014 and 31 May 2017, 942 consumer participants were recruited across the three time-points, 575 from PMHS and 367 from MHCSS. Overall recruitment targets were surpassed at each time-point (T0, T1 and T2) and most clusters were recruited into as planned (N=18 per cluster) at each time-point (see Figure 1 and
Table 1). As expected, overall recruitment rate from mailouts was low at 8·1% but yielding 622 or 66% of QPRs. Overall onsite recruitment rate as a proportion of all participants was 39·9% yielding 320 (34%) of all QPRs. As introduced above, consistency of recruitment strategies across time-points was important to successful implementation of the research design and percentages of QPRs derived from onsite recruitment were 32% at T0, 34% at T1 and 36% at T2. Table 1 describes each cluster including: organisation sector, stratification level, allocated intervention step, and number of consumer participants recruited at each time point.

Table 2 shows the consumer descriptions in the three cross-sectional surveys

Outcome modelling

In both streams 1 and 2 trials what eventuated were minimal repeated observations, and 90% of the data arose from singletons; therefore, specifying consumers as random was not done. In stream 1, over 90% of QPRs came from 854 individuals contributing to a single timepoint, plus there were 38 individuals contributing to two timepoint sand only 4 contributing to three timepoints. In stream 2, 90% of interviews were done by 245 individuals contributing to a single timepoint, and there were 12 individuals contributing to two timepoints.

Primary outcome

Table 6 show the intervention effects, which are estimated as the difference in the model adjusted means between the control and intervention data. This was 3.7 (95% Confidence interval: 1.2 – 6.3) for the primary outcome in the stream 1 trial, which was significantly greater than zero. See Table 7 for this model outputs, and see supplementary files for the model building results (see appendix 3). Another supplementary file (see appendix 4) shows the model outputs when including interaction terms, which showed that the difference in the model adjusted means increased slightly to 4.2 (95% CI: 1.1 – 7.2) and remained significantly greater than zero.

Mixed-effects model outputs in **Table 6** show that, after adjusting for age and gender and accounting for clustering, we find significant intervention and sector effects. Wald test results indicate significant interactions for model 1 (p=0·01), model 2 (p=0·02), model 3 (p<0·01), and model 4 (p<0·0001). AIC values indicated that model 2 provided the better fit. ICC for clusters was 0·046. Reference category, having the lowest QPR mean, is the no-intervention group at T1.

Error! Reference source not found. shows model-adjusted means for the QPR at each time-point and also raw data sample means. Overall, modelling showed significant intervention effects ($p<0·05$) reflected in pooled data by the non-intervention clusters mean decreasing 3-4 points at year 1 compared to baseline, and then improving back to baseline levels in year 2 once all clusters had received the intervention. Clusters receiving the intervention in year 1 did not exhibit this decrease in mean. While sector sub-group analyses showed PMHS findings were similar to the overall result, the MHCSS mean remained low in year 2.

Figure 2 shows QPR scores over time by sector. Pre/post intervention differences occur between T0 and T1 for step-one clusters, and between T1 and T2 for step-two clusters. Therefore, four pre/post intervention scenarios are depicted in this figure (two in each sector). Two of these showed evidence of a significant pre/post intervention difference in QPR scores: in the PMHS sector (2a), in the step-two group there was a significant difference between T1 and T2 of 4·9 (z-score=3·0, p=0·003); and in the MHCSS sector (2b), in the step-one group there was a significant difference between T0 and T1 of 1·1 (z-score=2·7, p=0·006).

Secondary and other outcomes

Ten results are shown in Table 6. Nine of these produced a mean change in the direction favouring the intervention. (No other study results collected have been examined). If the intervention had no effect, then the probability of each result favouring the direction of the intervention is 0.5 (i.e. half-and-half). Binomial probability theory tells us the probability of this occurring 9 times from 10 results is 0.0107. In other words, we can say that the intervention had an effect resulting in 9 of the 10 results producing a mean difference favouring the intervention, with p<0.01.

Discussion

Summary and interpretation of key findings

Recovery oriented practice (ROP) involves a set of practices through which mental health professionals employ skills, values, attitudes and behaviours that support individuals in their personal recovery(ref), for which positive change in consumer-rated experience of personal recovery is an important indicator. The PULSAR project found a small but statistically significant effect on consumer QPR scores for the REFOCUS-PULSAR staff training intervention, using the REFOCUS materials adapted to an Australian context, involving two service sectors and delivered in context of a stepped-wedge design. A significant interaction effect found for service sector suggests that the changes found in PMHS and MHCSS sectors are better considered separately. In PMHS, while there was no significant change from T0 to T1 for the step-one group, which might have been expected because they received the REFOCUS-PULSAR intervention during this time, there was a significant improvement from T1 to T2 (2·7 point increase in QPR scores) for the step-two group, through the time they received the REFOCUS-PULSAR intervention. In MHCSS, there was significant change in step-one clusters through their intervention period (T0-T1) and a positive, though not significant, trend in step-two clusters when their training was delivered. Taken together, these results provide evidence that the personal recovery of consumers can be supported by training and supporting mental health staff to implement recovery orientated practice (ref). It also contributes to providing the level of evidence for training described in the Kirkpatrick model as Level 4 Results that has to date often been missing from training interventions (Kirkpatrick et al 2006). A 2·7 point improvement in QPR score represents a 3% change in the full scale score. This unstandardized metric is the only effect-size reported here, as recommendations regarding the modelling approach used are that standardized effect sizes are easily distorted by factors unrelated to size of effect[27] and are not straightforward to interpret due to expected variance differences in the mixed model components.[28] Based on QPR questionnaire content, even changes of 1-2 points ,might be clinically meaningful. For instance a 2 point shift is achieved if the item 'I feel part of society rather than isolated' goes from neutral to strongly agree, which might represent a significant recovery outcome. The training team, working in a PDSA approach, made modifications to the training as delivered in step-two following feedback from step-one. These results seem to confirm that these modifications achieved an enhanced impact in step-two and that the REFOCUS-PULSAR intervention was associated with positive changes in QPR mean scores, most especially as refined for step-two and in the PMHS sector. While speculative, possible mechanisms that might have led to the improvements in the primary outcome in step two might be that the attention to relationship building between the

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- Ive added some points to the first paragraph.
- Some others that might be useful in discussion of the PULSAR training are on the following page

Commented [LB3]: Need to add more on the Kirkpatrick model

Commented [E4]: Slade M, Bird V, Clarke E, et al. Supporting recovery in patients with psychosis through care by community-based adult mental health teams (REFOCUS): a multisite, cluster, randomised, controlled trial. *Lancet Psychiatry* 2015; **2**(6): 503-14.

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Commented [E6]: Le Boutillier C, Leamy M, Bird VJ, Davidson L, Williams J, Slade M. What does recovery mean in practice? A qualitative analysis of international recovery-oriented practice guidance. *Psychiatr Serv* 2011; **62**: 1470–76.

person training who brought lived experience expertise and the professional trainer in delivery had the intended effect of providing better modelling of behaviour for participants through more clearly demonstrating respect for a lived experience perspective and advanced communication skills. Earlier availability of the manual may have improved uptake of principles for some participants while the team may also generally have gained experience with the delivery of both the core training and the PALS through time.

Stream-two findings of small effects, typically below the study power threshold, in the majority (9 of 10 comparisons) favoured the intervention condition, a finding unlikely to be due to chance. So the secondary and other outcome findings provide some support that the intervention made at least some level of positive difference across most of these measures.

Comparisons with REFOCUS

This study differed somewhat in design, setting and intervention from the REFOCUS work, while remaining closely related to it. Findings here are more positive overall than those from the REFOCUS study. The differences developed between PULSAR and REFOCUS including those based on learnings from the REFOCUS experience may all have influenced this. The literature on stepped-wedge designs had advanced in the period between design of REFOCUS and PULSAR and the adaptive nature of the PULSAR design allowed for refinements of the training following the first implementation to be evaluated. We note that if this study had been conducted with a similar parallel-group RCT design to that of REFOCUS, then without the inclusion of the step-two findings, PULSAR would not have yielded the positive findings reported here. The involvement of facilitators with lived experience of mental health issues and recovering is central to challenging conventional practices, and in making progress toward an effective recovery-oriented mental health workforce (Salkeld et al). This might be why we achieved more significant findings particularly in Step 2 when the interaction between co-facilitators had been further developed. To better understand how sustained practice change can be achieved within services, future ROP training initiatives are recommended to strengthen the focus on implementation strategies, such as follow up coaching or mentoring, refresher programs, and service user feedback and evaluation (Deane et al; Lodge et al; Stuber et al). Wide-ranging organisational factors are recognized as influential in supporting or constraining ROP implementation efforts (Le Boutillier et al; Lodge et al; Uppal et al), so that attention to organizational readiness for change and alignment of organizational policies, processes, staffing and resources with recovery oriented principles are also important.

Limitations

Accuracy of change-estimates might have been affected by the critical challenges facing the services as noted in the introduction. In both sectors the trend from T0 to T1 in the step-two group receiving no intervention in this time was of declining QPR scores, this most strongly in the MHCSS. Taking into account the challenging influences on all involved services, particularly MHCSS as noted in the 'Setting' section earlier and appendix ???, it may be that these were acting across the services to drive QPR scores down. If that effect were also operating in the teams at the time they were receiving the intervention, then the underlying trend there might have been towards declining QPR as well. In this case, the findings might be underestimating the effect of the REFOCUS-PULSAR intervention.

The training approach only managed to reach half of the staff and did not well engage with medical staff. It seems likely that this might have reduced the potency of the intervention. While we attempted to engage across the service with this staff group especially in step-two, this did not meet with great success. In future implementation of such training which would not be working within constraints of such study designs, either more effective engagement of medical staff in team-based training, or better alignment with their profession-specific training expectations would, *a-priori* be likely to achieve better results.

Our recruitment strategy of repeated sampling and direct consumer approaches was chosen for the strengths of avoiding clinician discretion as a key action-point for selection bias, enhancing consumer autonomy in participation,[30] and of avoiding selection bias towards greater chronicity of course of illness, identified as a problem in REFOCUS. However, while we have documented the considerable efforts gone to towards consistency of recruitment strategies, the possibility that this created time-variant selection bias on findings cannot be excluded. The circumstances of the organisations and the findings noted above would suggest that in absence of intervention QPR scores in the consumer sample frame might have been typically going down and in that case, the likely influence of these changes would be to reduce the size of observed effects, not increase them.

Specific service recommendations

Recovery has emerged as a core feature of contemporary reform to mental health service planning and delivery and can be identified in mental health policy, practice and law in all Australian states and territories. This process has been largely driven by societal values - "cultural rationality" {Gibson, 2003 #335} rather than evidence and so, as noted by Slade et al., {, 2015 #9}, policy has been "substantially ahead of research and practice" (p. 503). This study offers some reassurance that ROP, particularly as implemented in PULSAR step 2, can be effectively implemented in alignment with current policy. While our findings are modest, this is not surprising in a pragmatic trial (ref) and they are in a direction of positive change for consumers. They also add to the evidence base for a recovery orientation {Warner, 2010 #337} and the positive findings in REFOCUS for high participation teams. This study adds to the empirical support for the role of staff training in the transformation of services towards recovery-oriented systems of care (Slade et al., 2014). Taken together, the available evidence at the very least provides no reason why training in ROP should not continue to be made available to support staff to deliver care in accordance with government policy and law. Requests from services for further PULSAR training are in alignment with recommendations made from the study team to PMHS and MHCSS service partners to rerun the cycle of REFOCUS-PULSAR training three times in the next year, extending and adapting the training to include inpatient staff so that the recovery-oriented culture can extend more widely across the care spectrum; and work to increase the integration of REFOCUS-PULSAR documents with organisation record systems and forms. These have all been accepted by participating organisations and prompts related to the REFOCUS-PULSAR frameworks are now integrated into the PMHS treatment and recovery plan documentation.

Conclusions

This intervention was effective in promoting ROP across sectors, though this effect was only clearly seen in Public Mental Health Services after the training had been refined. The intervention should be considered for services as part of broader organisation-wide initiatives to promote recovery-oriented practice.

Contributors

GM was the Principal Investigator on this trial and together with JE led development of key elements of the design and analysis approach and interpretation of the findings. MS developed the original REFOCUS intervention and advised on adaptation. LB chaired the research module task-group and

provided oversight to development and implementation of all elements of the design. FS provided overall coordination for field work and staff training and was centrally involved in the day-to-day operations of trial implementation. JE conducted the analyses. Specialist contributions regarding design elements were made by EF and EWE. CT contributed to the study design and implementation within MHCSS and was a chair of the adaptation module task-group. PW chaired the implementation module task-group which oversaw the delivery of the training intervention. VE, LB, GM, PW and EWE developed the specific specialist care training intervention and associated resources. GM, LB, FS, VE and EWE developed the specialist care instrumentation and fieldwork trial protocols. The core drafting group for this paper comprised GM, LB, FS, JE, MS; the remaining authors revised it critically for important intellectual content. All authors read and gave final approval for this version of the paper to be published.

Declaration of interests

We declare no competing interests.

Data sharing statement

In compliance with the requirements of the Monash Health Research Ethics Committee, the data supporting our findings in the manuscript will not be shared because we did not obtain participant consent to do so.

Acknowledgements

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Tables and Figures

Table 1 consumer numbers by cluster, stratification levels, intervention step and timepoint

(a) Stream 1 trial numbers of consumer participants in the three cross-sectional surveys who completed the Questionnaire about the Process of Recovery (QPR)

Cluster	Site information Organisation	Strata	N	%	QPR surveys T0	T1	T2
1	PMHS	A	66	7·0	23	29	14
2	PMHS	B	37	3·9	14	12	11
3	PMHS	C	66	7·0	21	24	21
4	PMHS	D	104	11·0	32	38	34
5	MHCSS - 1	E	52	5·5	16	15	21
6	MHCSS – 2	F	64	6·8	20	17	17
7	MHCSS - 1	G	56	5·9	19	25	12
8	PMHS	A	98	10·4	30	26	42
9	PMHS	B	44	4·7	17	15	12
10	PMHS	C	89	9·5	21	41	27
11	PMHS	D	71	7·5	20	26	25
12	MHCSS - 1	E	69	7·3	21	24	24
13	MHCSS – 2	F	52	5·5	21	17	14
14	MHCSS – 2	G	74	7·9	26	25	23
	Total, All sectors		*942*	*100*	*301*	*334*	*307*

Notes. Clusters were stratified by the team/service type and composition: i.e. seven different st. Overall there were 575 (61·0%) consumer QPR surveys from Public Mental Health Services (PMHS) and 367 (39·0%) from Mental Health Community Support Services (MHCSS): 177 (18·8%) from MHCSS-1 and 190 (20·2%) from MHCSS-2.

(a) Stream 2 trial numbers of consumer participants who participated in a study interview.

Cluster	Site information Organisation	Strata	N	%	QPR surveys T0	T1	T2
2	PMHS	A	22	8.1	10	12	-
4	PMHS	B	15	5.5	10	5	-
5	PMHS	C	17	6.2	6	11	-
7	PMHS	D	24	8.8	14	10	-
10	MHCSS - 1	E	11	4.0	9	2	-
11	MHCSS – 2	F	19	7.0	11	8	-
13	MHCSS - 1	G	23	8.4	11	12	-
1	PMHS	A	26	9.5	-	13	13
3	PMHS	B	7	2.3	-	5	2
6	PMHS	C	29	10.6	-	12	17
8	PMHS	D	16	5.7	-	9	7
9	MHCSS - 1	E	23	8.4	-	9	14
12	MHCSS – 2	F	18	6.6	-	12	6
14	MHCSS – 2	G	23	8.4	-	9	14
	Total, All sectors		*273*	*100*	*71*	*129*	*73*

Notes. Clusters were stratified by the team/service type and composition: i.e. seven different strata. Overall there were 6 (57.1%) interviews with consumers from Public Mental Health Services (PMHS) and 117 (42.9%) from Mental Health Community Support Services (MHCSS): 57 (20.9%) from MHCSS-1 and 60 (22%) from MHCSS-2.

Key:
Control condition period
Intervention condition period

Table 2 Stream 1 trial QPR numbers (%) by timepoint, gender, age group, step, intervention status and demographics

	Time Point			
	T0	**T1**	**T2**	**Total**
Distribution in specialist care by Time Point				
N	301	334	307	942
(%)	(32·0)	(35·5)	(32·6)	(100)
Distribution in specialist care by Time Point and Gender[1]				
Female	174 (57.8)	192 (57.5)	178 (58.0)	544 (57.7)
Male	125 (41.5)	139 (41.6)	126 (41.0)	390 (41.4)
Not listed	2 (0.7)	3 (0.9)	3 (1.0)	8 (0.8)
Distribution in specialist care by Time Point and Age group				
17-30 years	73 (24.3)	77 (23.1)	79 (25.7)	229 (24.3)
30–49 years	151 (50.2)	170 (50.9)	151 (49.2)	472 (50.1)
50 years and over	72 (23.9)	84 (25.1)	74 (24.1)	230 (24.4)
Distribution in specialist care by Time Point and Step Group intervention				
Step Group 1	145 (48.2)	160 (47.9)	140 (45.6)	445 (47.2)
Step Group 2	156 (51.8)	174 (52.1)	167 (54.4)	497 (52.8)
Distribution in specialist care by Time Point and Intervention status (Ix)				
No Ix	301 (100)	174 (52.1)	0 (0.0)	475 (50.4)
Yes Ix	0 (0)	160 (49.9)	307 (100)	467 (49.6)
Distribution in specialist care by Country of birth				
Australia	217 (72.1)	244 (73.1)	229 (74.6)	690 (73.2)
Other	83 (27.6)	87 (26.0)	73 (23.8)	243 (25.8)
Not listed	1 (0.4)	3 (0.9)	5 (1.6)	9 (1.0)
Distribution in specialist care by Year of arrival				
After 2000	17 (5.6)	23 (6.9)	19 (6.2)	59 (6.3)
Between 1981-2000	40 (13.3)	39 (11.7)	27 (8.8)	106 (11.3)
Before 1980	18 (6.0)	17 (5.1)	17 (5.5)	52 (5.2)
Not listed	8 (2.7)	8 (2.4)	10 (3.3)	26 (2.8)
Distribution in specialist care by Main language				
English	265 (88.0)	286 (85.6)	269 (87.6)	820 (87.0)
Other	23 (7.6)	26 (7.8)	23 (7.5)	72 (7.6)
Both English and Other	8 (2.7)	17 (5.1)	7 (2.3)	32 (3.4)
Not listed	5 (1.7)	5 (1.5)	8 (2.6)	18 (1.9)
Distribution in specialist care by Ethnicity (self-identified)				
Australian Non-Indigenous	121 (40.2)	177 (53.0)	162 (52.8)	460 (48.8)
Australian Indigenous	27 (9.0)	20 (6.0)	33 (10.7)	80 (8.5)
Other	120 (39.9)	126 (37.7)	97 (31.6)	343 (36.4)
Not listed	33 (11.0)	11 (3.3)	15 (4.9)	59 (6.3)
Other category (multiple responses could be listed)				
English, Irish, Walsh, Scottish	25 (8.3)	42 (12.6)	29 (9.4)	96 (10.2)
Italian	13 (4.3)	17 (5.1)	10 (3.3)	40 (4.2)
Greek	7 (2.3)	17 (5.1)	11(3.6)	35 (3.7)
New Zealander/Maori	11 (3.7)	10 (3.0)	12 (3.9)	33 (3.5)
Other (participant selected "other")	72 (23.9)	58 (17.4)	33 (10.7)	163 (17.3)
Censored[2]	108 (35.9)	91 (27.2)	76 (24.8)	275 (29.2)
Distribution in specialist care by Duration of mental health service use				
Mean number of years	4·0	4·5	4·0	4·2
Median number of years	1·0	1·0	1·0	1·0
Range (years)	0-35	0-35	0-35	0-35
No. of people with <1 year at site	129 (42.9)	125 (37.4)	135 (44.0)	389 (42.3)
Mean number of months for those with <1 year at site	3·3	3·2	3·2	3·2
Median number of months for those with <1 year at site	3	3	3	3

Note. Where cell sizes are less than 5 at any time point for a given characteristic, data were pooled to ensure confidentiality.

[1]Gender was determined by asking participants: "Which gender do you identify with?" with options being Male, Female, Other

[2]Included 56 additional ethnic groups

Commented [JE7]: Added % as requested by reviewer

Table 3 NEW TABLE St 23 1 trial QPR numbers (%) by Intervention Status, gender, age group, step, intervention status and demographics. There were no significant differences between the control and intervention groups.

	Control	Intervention	Total
Distribution in specialist care			
N	475	467	942
(%)	(50.4·0)	(49·6)	(100)
Distribution in specialist care by Gender[1]			
Female	268 (56.4)	276 (59.1)	544 (57.7)
Male	203 (42.7)	187 (40.0)	390 (41.4)
Not listed	4 (0.8)	4 (0.9)	8 (0.8)
Distribution in specialist care by Age group			
17-30 years	104 (22.2)	125 (26.1)	229 (24.3)
30-49 years	243 (51.8)	229 (49.6)	472 (50.1)
50 years and over	122 (26.0)	108 (23.4)	230 (24.4)
Distribution in specialist care by Step Group intervention			
Step Group 1	145 (30.5)	300 (64.2)	445 (47.2)
Step Group 2	330 (69.5)	167 (35.8)	497 (52.8)
Distribution in specialist care by Intervention status (Ix)			
No Ix	475 (100)	0 (0.0)	475 (50.4)
Yes Ix	0 (0)	467 (100)	467 (49.6)
Distribution in specialist care by Country of birth			
Australia	345 (72.6)	345 (73.9)	690 (73.2)
Other[2]	125 (26.3)	118 (25.3)	243 (25.8)
Not listed	5 (1.1)	4 (0.9)	9 (1.0)
Distribution in specialist care by Year of arrival			
After 2000	27 (45.8)	32 (54.2)	59 (6.3)
Between 1981-2000	62 (58.5)	44 (41.5)	106 (11.3)
Before 1980	27 (54.0)	25 (46.0)	52 (5.2)
Not listed	12 (46.2)	14 (53.8)	26 (2.8)
Distribution in specialist care by Main language			
English	422 (88.8)	398 (85.2)	820 (87.0)
Other	32 (6.7)	40 (8.6)	72 (7.6)
Both English and Other	14 (2.9)	18 (3.9)	32 (3.4)
Not listed	7 (1.5)	11 (2.4)	18 (1.9)
Distribution in specialist care by Ethnicity (self-identified)			
Australian Non-Indigenous	223 (46.9)	237 (64.6)	460 (48.8)
Australian Indigenous	35 (7.4)	45 (12.3)	80 (8.5)
Other	176 (37.1)	167 (45.5)	343 (36.4)
Not listed	41 (8.6)	18 (4.9)	59 (6.3)
Distribution in specialist care by Duration of mental health service use			
Mean number of years	4·3	4·0	4·2
Median number of years	1·0	1·0	1·0
Range (years)	0-35	0-35	0-35
No. of people with <1 year at site	190 (40.0)	199 (42.6)	389 (42.3)
Mean number of months for those with <1 year at site	3·1	3·3	3·2
Median number of months for those with <1 year at site	3	3	3

Note. Where cell sizes are less than 5 at any time point for a given characteristic, data were pooled to ensure confidentiality.
[1]Gender was determined by asking participants: "Which gender do you identify with?" with options being Male, Female, Other

[2]Included 60 additional ethnic groups

Commented [JE8]: Included in response to reviewer

Commented [JE9]: I suggest that we delete this bit (also delete in the Stream 2 table)

Commented [JE10]: I suggest that we consider deleting this (also delete in the Stream 2 table)

Table 4 NEW TABLE Stream 2 trial QPR numbers (%) by timepoint, gender, age group, step, intervention status and demographics

Commented [JE11]: Included in response to reviewer

	Time Point			
	T0	**T1**	**T2**	**Total**
Distribution in specialist care by Time Point				
N	71	129	73	273
(%)	(26.0)	(47.3)	(26.7)	(100)
Distribution in specialist care by Time Point and Gender[1]				
Female	46 (64.8)	63 (48.8)	42 (57.5)	151 (55.3)
Male	25 (35.2)	64 (49.6)	31 (42.5)	120 (44)
Other	0 (0.0)	2 (1.6)	0 (0.0)	2 (0.7)
Distribution in specialist care by Time Point and Age group				
17-30 years	26 (36.6)	23 (17.8)	13 (17.8)	62 (22.7)
30-49 years	30 (42.3)	67 (51.9)	35 (48)	132 (48.4)
50 years and over	15 (21.1)	38 (29.5)	24 (32.9)	77 (28.2)
Not listed	0 (0.0)	1 (0.8)	1 (1.4)	2 (0.7)
Distribution in specialist care by Time Point and Step Group intervention				
Step Group 1	71 (100)	60 (46.5)	0 (0.0)	131 (48)
Step Group 2	0 (0.0)	69 (53.5)	73 (100)	142 (52)
Distribution in specialist care by Time Point and Intervention status (Ix)				
No Ix	71 (100)	69 (53.5)	0 (0.0)	140 (51.3)
Yes Ix	0 (0.0)	60 (46.5)	73 (100)	133 (48.7)
Distribution in specialist care by Country of birth				
Australia	49 (69.0)	94 (72.9)	53 (72.6)	196 (71.8)
Other	22 (31.0)	35 (27.1)	20 (27.4)	77 (28.2)
Year of arrival in Australia				
After 2000	2 (9.1)	11 (18.3)	2 (10.0)	15 (19.5)
Between 1981-2000	12 (54.5)	14 (23.3)	10 (50.0)	36 (46.8)
Before 1980	6 (27.3)	10 (16.7)	7 (35.0)	23 (29.9)
Not listed	2 (9.1)	25 (41.7)	1 (5.0)	28 (36.4)
Distribution in specialist care by Main language spoken at home				
English	60 (84.5)	115 (89.2)	66 (90.4)	241 (88.3)
Other	11 (15.5)	14 (10.9)	7 (9.6)	32 (11.7)
Distribution in specialist care by Ethnicity (self-identified)				
Australian Non-Indigenous	38 (53.5)	74 (57.4)	43 (58.9)	155 (56.8)
Australian Indigenous	2 (2.8)	2 (1.6)	2 (2.7)	6 (2.2)
Other	20 (28.2)	50 (38.8)	19 (26)	89 (32.6)
Not listed	11 (15.5)	3 (2.3)	9 (12.3)	23 (8.4)
Other category (multiple responses could be listed)				
British (English, Irish, Walsh, Scottish)	1 (5.0)	17 (34.0)	5 (26.3)	23 (25.8)
European (Italian, Greek, Bosnian, Dutch, German)	7 (35.0)	20 (40.0)	5 (26.3)	32 (36.0)
New Zealander/Maori	2 (10.0)	3 (6.0)	4 (21.1)	9 (10.1)
Middle Eastern (Afghan)	2 (10.0)	0 (0.0)	0 (0.0)	2 (2.2)
South East Asian (Burmese, Chinese, Indian, Cambodian, Sri Lankan, Vietnamese)	8 (16.0)	5 (10.0)	5 (26.3)	18 (20.2)
Other (participant selected "other")	0 (0.0)	5 (10.0)	0 (0.0)	5 (5.6)
Distribution in specialist care by Duration of mental health service use				
Mean number of years	11.0	13.2	13.1	12.6
Median number of years	9·0	11·0	11·0	10·0
Range (years)	1-40	1-33	1-40	1-40
No. of people with <1 year at site	0	0	0	0
Duration of current service use				
Mean number of years	4.6	5.8	7.2	5.8
Median number of years	3·0	3·0	4.5	3·0
Range (years)	0-23	1-22	1-32	0-32
No. of people with <1 year at site	1	0	0	1
Median number of months for those with <1 year at site	3	-	-	3
Distribution in specialist care by Marital status				
Single	48 (67.6)	67 (51.9)	33 (45.2)	148 (54.2)
Married	6 (8.5)	21 (16.3)	16 (21.9)	43 (15.8)
DeFacto	3 (4.2)	8 (6.2)	1 (1.4)	12 (4.4)
Separated	4 (5.6)	15 (11.6)	10 (13.7)	29 (10.6)
Divorced	10 (14.1)	14 (10.9)	10 (13.7)	34 (46.6)
Widowed	0 (0.0)	1 (0.8)	2 (2.7)	3 (4.1)
Other	0 (0.0)	3 (2.3)	1 (1.4)	4 (5.5)
Distribution in specialist care by Child status				
Yes	33 (46.5)	64 (49.6)	41 (56.2)	138 (50.5)
No	38 (53.5)	65 (50.4)	32 (43.8)	135 (49.5)
Number of children living at home				
0	16 (48.5)	32 (50.0)	16 (39.0)	64 (46.4)
1	11 (33.3)	17 (26.6)	12 (29.3)	40 (29.0)
2	4 (12.2)	10 (15.6)	9 (22.0)	23 (16.7)
3	0 (0.0)	1 (1.6)	3 (7.3)	4 (2.9)
4	1 (3.0)	1 (1.6)	0 (0.0)	2 (1.4)
5-6	1 (3.0)	1 (1.6)	0 (0.0)	2 (1.4)
Not listed	0 (0.0)	2 (3.1)	1 (2.4)	3 (2.2)

Distribution in specialist care by Living situation (multiple responses could be selected)				
Living with parents	16 (22.5)	16 (12.4)	15 (20.5)	47 (17.2)
Living with siblings	4 (5.6)	8 (6.2)	4 (5.5)	16 (5.9)
Living with a partner	7 (9.9)	31 (24.0)	15 (20.5)	53 (19.4)
Living with children	15 (21.1)	26 (20.2)	19 (26.0)	60 (22.0)
Living with friends	4 (5.6)	7 (5.4)	2 (2.7)	13 (4.8)
Living in shared accommodation	5 (7.0)	14 (10.9)	5 (6.8)	24 (8.8)
Living in crisis accommodation	3 (4.2)	3 (2.3)	1 (1.4)	7 (2.6)
Living in support housing	8 (11.3)	11 (8.5)	9 (12.3)	28 (10.3)
Living alone	23 (32.4)	30 (23.3)	20 (27.4)	73 (26.7)
Homeless	3 (4.2)	3 (2.3)	0 (0.0)	6 (2.2)
Other	4 (5.6)	10 (7.8)	1 (1.4)	15 (5.5)
Distribution in specialist care by Education level				
None	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.4)
Primary school	2 (2.8)	4 (3.1)	0 (0.0)	6 (2.2)
Secondary school (≤ yr 10)	25 (35.2)	39 (27.9)	21 (28.8)	85 (31.1)
Secondary school (yr 11)	12 (16.9)	30 (23.3)	14 (19.2)	56 (20.5)
Secondary school (yr 12)	27 (38.0)	56 (43.4)	37 (50.7)	120 (44.0)
Not listed	5 (7.0)	0 (0.0)	0 (0.0)	5 (1.8)
Distribution in specialist care by Highest qualification				
Certificate I	2 (2.8)	1 (0.8)	1 (1.4)	4 (1.5)
Certificate II	3 (4.2)	6 (4.7)	4 (5.5)	13 (4.8)
Certificate III	15 (21.1)	19 (14.7)	13 (17.8)	47 (17.2)
Certificate IV	7 (9.9)	15 (11.6)	10 (13.7)	32 (11.7)
Diploma	9 (12.7)	11 (8.5)	10 (13.7)	30 (11.0)
Advanced Diploma	1 (1.4)	1 (0.8)	1 (1.4)	3 (1.1)
Associate Degree	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.4)
Bachelor Degree	1 (1.4)	13 (10.1)	7 (9.6)	21 (7.7)
Bachelor Honours Degree	0 (0.0)	3 (2.3)	1 (1.4)	4 (1.5)
Graduate Diploma	0 (0.0)	2 (1.6)	2 (2.7)	4 (1.5)
Masters (research)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.4)
Masters (coursework)	1 (1.4)	3 (2.3)	1 (1.4)	5 (1.8)
Doctoral	1 (1.4)	1 (0.8)	0 (0.0)	2 (0.7)
Other	3 (2.8)	11 (8.5)	4 (5.5)	18 (6.6)
Not listed	28 (39.4)	41 (31.8)	19 (26.0)	85 (31.1)

Note. Where cell sizes are less than 5 at any time point for a given characteristic, data were pooled to ensure confidentiality.
[1]Gender was determined by asking participants: "Which gender do you identify with?" with options being Male, Female, Other

Table 5 NEW TABLE Stream 2 trial QPR numbers (%) by Intervention Status, gender, age group, step, intervention 23 s and demographics.

There were no significant differences between the control and intervention groups.

	Control	Intervention	Total
Distribution in specialist care			
N	140	133	273
(%)	(51.3)	(48.7)	(100)
Distribution in specialist care by Gender[1]			
Female	80 (57.1)	71 (53.4)	151 (55.3)
Male	59 (42.1)	61 (45.9)	120 (44)
Not listed	1 (0.7)	1 (0.8)	2 (0.7)
Distribution in specialist care by Age group			
17-30 years	35 (25.0)	27 (20.3)	62 (22.7)
30-49 years	65 (46.4)	67 (50.4)	132 (48.4)
50 years and over	39 (27.9)	38 (28.6)	77 (28.2)
Not listed	1 (0.7)	1 (0.8)	2 (0.7)
Distribution in specialist care by Step Group intervention			
Step Group 1	71 (50.7)	60 (45.1)	131 (48.0)
Step Group 2	69 (49.3)	73 (54.9)	142 (52.0)
Distribution in specialist care by Intervention status (Ix)			
No Ix	140 (100)	0 (0.0)	140 (50.4)
Yes Ix	0 (0.0)	133 (100)	133 (49.6)
Distribution in specialist care by Country of birth			
Australia	98 (70.0)	98 (73.7)	196 (71.8)
Other[2]	42 (30.0)	35 (26.3)	77 (28.2)
Year of arrival in Australia			
After 2000	8 (19.0)	7 (20.0)	15 (19.5)
Between 1981-2000	20 (47.6)	16 (45.7)	36 (46.8)
Before 1980	12 (28.6)	11 (31.4)	23 (29.9)
Not listed	2 (4.8)	1 (2.9)	3 (3.9)
Distribution in specialist care by Main language			
English	124 (88.6)	117 (88.0)	241 (88.3)
Other	16 (11.4)	16 (12.0)	32 (11.7)
Distribution in specialist care by Ethnicity (self-identified)			
Australian Indigenous	2 (1.4)	4 (3.0)	6 (2.2)
Australian Non-Indigenous	77 (55.0)	78 (58.6)	155 (56.8)
Other	54 (38.6)	35 (26.3)	89 (32.6)
Not listed	7 (5.0)	16 (12.0)	23 (8.4)
Other category (multiple responses could be listed)			
British (English, Irish, Walsh, Scottish)	13 (24.1)	10 (28.6)	23 (25.8)
European (Italian, Greek, Bosnian, Dutch, German)	22 (40.7)	10 (28.6)	32 (36.0)
New Zealander/Maori	4 (7.4)	5 (14.3)	9 (10.1)
Middle Eastern (Afghan)	2 (3.7)	0 (0.0)	2 (2.2)
South East Asian (Burmese, Chinese, Indian, Cambodian, Sri Lankan, Vietnamese)	13 (24.1)	10 (28.6)	23 (25.8)
Other (participant selected "other")	0 (0.0)	0 (0.0)	0 (0.0)
Distribution in specialist care by Duration of mental health service use			
Mean number of years	13.1	12.0	`12.6
Median number of years	10·0	10·0	10·0
Range (years)	1-40	1-40	1-40
No. of people with <1 year at site10 (28.6)	0	0	0
Duration of current service use			
Mean number of years	5.2	6.5	5.8
Median number of years	3.0	4.0	3.0
Range (years)	0-23	1-32	0-32
No. of people with <1 year at site	1	0	1
Number of months for those with <1 year at site	3	-	3
Distribution in specialist care by Marital status			
Single	77 (55.0)	71 (53.4)	148 (54.2)
Married	20 (14.3)	23 (17.3)	43 (15.8)
DeFacto	10 (7.1)	2 (1.5)	12 (4.4)
Separated	15 (10.7)	14 (10.5)	29 (10.6)
Divorced	17 (12.1)	17 (12.8)	34 (12.5)
Widowed	0 (0.0)	3 (2.3)	3 (1.1)
	1 (0.7)	3 (2.3)	4 (1.5)
37 bution in specialist care by Child status			
Yes	76 (54.3)	62 (46.6)	138 (50.5)
No	64 (45.7)	71 (53.4)	135 (49.5)
Number of children living at home			
0	39 (51.3)	25 (40.3)	64 (46.4)
1	11 (14.5)	21 (33.9)	32 (23.2)
2	12 (15.8)	11 (17.7)	23 (16.7)
3	2 (2.6)	3 (4.8)	5 (3.6)
4	2 (2.6)	0 (0.0)	2 (1.4)
5-6	1 (1.3)	0 (0.0)	1 (0.7)

Commented [JE12]: Included in response to reviewer

Commented [JE13]: Suggest removing

Commented [LB14R13]: Is that due to change in analysis?

Commented [JE15]: Suggest removing

Commented [LB16R15]: Ditto?

Not listed	37 (48.7)	2 (3.2)	39 (28.2)
Distribution in specialist care by Living situation (multiple responses could be selected)			
Living with parents	21 (15.0)	26 (19.5)	47 (17.2)
Living with siblings	8 (5.7)	8 (6.0)	16 (5.9)
Living with a partner	29 (20.7)	24 (18.0)	53 (19.4)
Living with children	31 (22.1)	29 (21.8)	60 (22.0)
Living with friends	6 (4.3)	7 (5.3)	13 (4.8)
Living in shared accommodation	12 (8.6)	12 (9.0)	24 (8.8)
Living in crisis accommodation	6 (4.3)	1 (0.8)	7 (2.6)
Living in support housing	12 (8.6)	16 (12.0)	28 (10.3)
Living alone	38 (27.1)	35 (12.8)	73 (26.7)
Homeless	4 (2.9)	2 (1.5)	6 (2.2)
	12 (8.6)	3 (2.3)	15 (5.5)
bution in specialist care by Education level			
None	0 (0.0)	1 (0.8)	1 (0.4)
Primary school	4 (2.9)	2 (1.5)	6 (2.2)
Secondary school (≤ yr 10)	46 (32.9)	39 (29.3)	85 (31.1)
Secondary school (yr 11)	30 (21.4)	26 (19.5)	56 (42.1)
Secondary school (yr 12)	55 (39.3)	65 (48.9)	120 (44.0)
Not listed	5 (3.6)	0 (0.0)	5 (1.8)
Distribution in specialist care by Highest qualification			
Certificate I	2 (1.4)	2 (1.5)	4 (1.5)
Certificate II	7 (5.0)	6 (4.5)	13 (4.8)
Certificate III	26 (18.6)	21 (15.8)	47 (17.2)
Certificate IV	14 (10.0)	18 (13.5)	32 (11.7)
Diploma	18 (12.9)	12 (9.0)	30 (11.0)
Advanced Diploma	1 (0.7)	2 (1.5)	3 (1.1)
Associate Degree	0 (0.0)	1 (0.8)	1 (0.4)
Bachelor Degree	8 (5.7)	13 (9.8)	21 (7.7)
Bachelor Honours Degree	1 (0.7)	3 (2.3)	4 (1.5)
Graduate Diploma	2 (1.4)	2 (1.5)	4 (1.5)
Masters (research)	1 (0.7)	0 (0.0)	1 (0.4)
Masters (coursework)	2 (1.4)	3 (2.3)	5 (1.8)
Doctoral	1 (0.7)	1 (0.8)	2 (0.7)
Other	9 (6.4)	9 (6.8)	18 (6.6)
Not listed	48 (34.3)	40 (30.1)	88 (32.2)

Note. Where cell sizes are less than 5 at any time point for a given characteristic, data were pooled to ensure confidentiality.
[1]Gender was determined by asking participants: "Which gender do you identify with?" with options being Male, Female, Other

Table 6 NEW TABLE Summary of outcomes in the streams 1 and 2 trials. Mean and standard deviation (sd) unless otherwise indicated. [d] Also shown are the adjusted differences calculated from the multi-level mixed models ([d] linear or [II] Poisson regressions) adjusted for fixed effects of gender, age, timepoint and sector and clusters as random effects. Step group is an additional fixed effect in the stream 1 regressions.

Primary outcome:		**Control (n=475)**	**Intervention (n=467)**	**Adjusted diff in means (95%CI); p-value**	**Change in direction of favouring the intervention**
QPR Stream 1	Mean (sd)	53.6 (16.3); n=475	54.4 (16.2); n=467	3.72 [d] (0.51,6.92); 0.023	YesYes
Secondary outcomes:		**Control (n=140)**	**Intervention (n=133)**		
QPR Stream 2	Mean (sd)	53.1 (14.8); n=138	54.0 (14.5); n=131	2.54[d] (-3.10,8.18); 0.38	
Warrick	Mean (sd)	41.4 (11.2); n=139	42.2 (11.1); n=133	2.39 [d] (-2.66,7.43); 0.35	Yes
Inspire S score	Mean (sd)	62.4 (22.3); n=128	62.2 (23.1); n=123	2.03 [d] (-6.72,10.78); 0.65	Yes
Inspire R score	Mean (sd)	72.0 (22.3); n=134	75.5 (20.1); n=129	3.29 [d] (-3.39,9.97); 0.34	
Other outcomes:		**Control (n=140)**	**Intervention (n=133)**		
GAF score	Mean (sd)	48.5 (14.7); n=140	51.4 (13.3); n=133	0.92 [d] (-6.15, 8.00); 0.80	Yes
SOFA score	Mean (sd)	49.8 (15.5); n=134	52.9 (14.3); n=132	0.57 [d] (-5.30, 6.45); 0.85	Yes
Client Satisfaction Questionnaire (CSQ)	Mean (sd)	23.3 (5.3); n=139	24.5 (5.5); n=130	1.21 [d] (-0.98, 3.41); 0.28	Yes
Mind Australia Satisfaction Survey (MASS)	Mean (sd)	8.0 (1.8); n=140	8.2 (1.8); n=132	0.02 [d] (-0.62, 0.67); 0.94	Yes
The Coercion Ladder, Community services	Median (IQR)	2.0 (1.5); n=139	2.0 (1.5); n=139	0.20 [II] (-1.12, 0.72); 0.67	Yes
The Coercion Ladder, Hospital inpatient					
Days out of role (full)	Median (IQR)	6.5 (0.0,15.0); n=138	6.0 (0.0,15.0); n=133	-1.37 (-5.34, 2.59); 0.50	No
Days out of role (partial)	Median (IQR)	6.0 (0.0,15.0); n=133	10.0 (2.0,15.0); n=129	0.12 (-4.56, 4.81); 0.96	
INCO					Yes

Commented [JE17]: Included in response to reviewers comments about not being able to follow the results

Commented [LB18R17]: Needs to be 10 results

Commented [JE19]: See appendix 2 for these results

Commented [LB20]: In results

Table 7 NEW TABLE **Stream 1 QPR** mixed model with fixed factors of sector, step-group, sex, age-group, timepoint and intervention status, and clusters as random. Number of obs=942
*** p<0.01, ** p<0.05, * p<0.1

Commented [JE21]: Included in response to reviewers comments about not being able to follow the results

		b	se	z	pvalue	ll	ul
sex							
	Female	-0.81	1.04	-0.79	.431	-2.84	1.21
Age group							
	2	-0.94	0.88	-1.07	.285	-2.65	0.78
	3	-3.4	0.91	-3.78	0.001***	-5.22	-1.66
Timepoint							
	T1	-3.22	1.02	-3.16	.002***	-5.22	-1.22
	T2	-4.22	1.50	-2.82	.005***	-7.15	-1.29
Intervention status							
	yes	3.76	1.31	2.87	.004***	1.20	6.33
Sector							
	2	-1.72	2.12	-0.81	.418	-5.87	2.43
Step group							
	2	0.15	2.08	0.07	.943	-3.93	4.22

Model adjusted QPR means

		QPR mean	Std.Err.	[95%Conf.	Interval]
sex					
	1	54.85	1.36	52.18	57.51
	2	54.03	1.23	51.63	56.44
age_cat					
	1	55.69	1.17	53.39	57.99
	2	54.75	1.25	52.31	57.20
	3	52.25	1.48	49.34	55.16
Timepoint					
	0	56.89	1.25	54.45	59.34
	1	53.67	1.43	50.86	56.48
	2	52.67	1.38	49.97	55.37
Intervention status					
	0	52.51	1.46	49.65	55.37
	1	56.27	1.23	53.87	58.67
sector					
	1	55.05	1.75	51.62	58.47
	2	53.33	1.24	50.91	55.75
step					
	1	54.29	1.42	51.52	57.07
	2	54.44	1.69	51.12	57.76

*The mean difference between treatment and control groups was 3·7 (95% Confidence interval: 0.5 – 6·8).

Figures

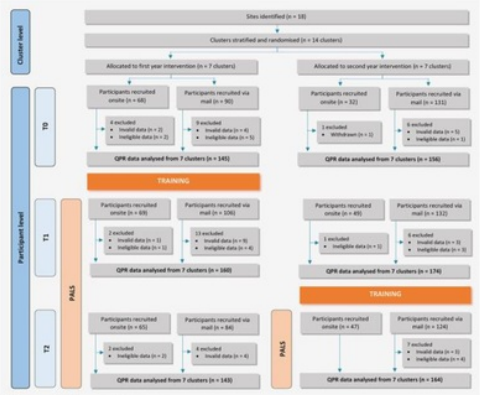
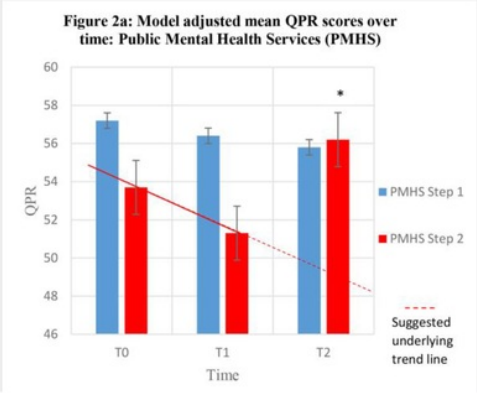


Figure 1 Consort Chart
Note. PALS = PULSAR Active Learning Sessions



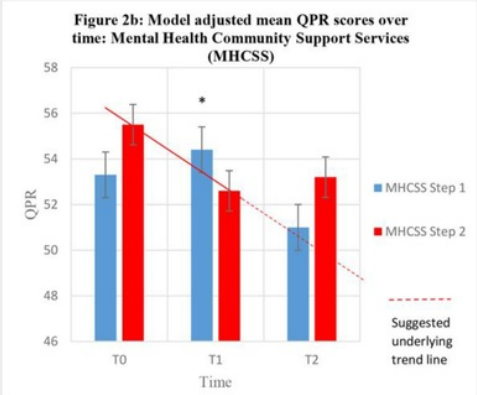


Figure 2 QPR scores by sector over time.

*Change $p < .01$ by pairwise comparison with previous time-point.
Note. Step-one group (blue) received intervention in year 1. Step-two group (red) received intervention in year 2.

Commented [LB22]: Underlying trend lines need to be removed

Supplementary figure

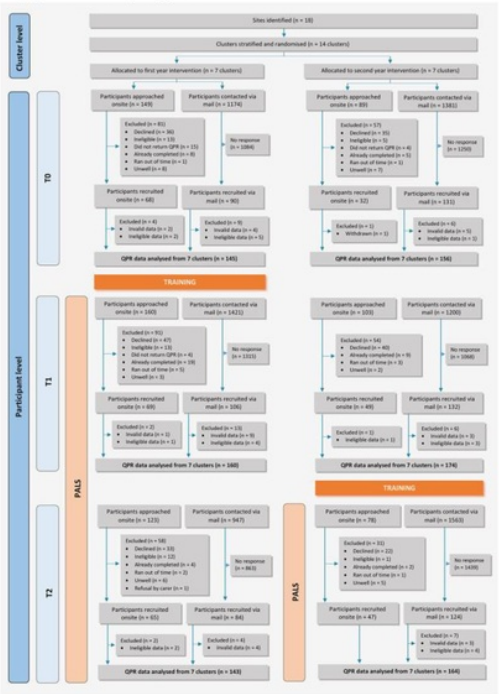


Figure S1: Detailed CONSORT chart
Note. PALS = PULSAR Active Learning Sessions

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Appendix 1

The first intervention round for clinical services was developed as a two-day session, with the community services training planned as a separate two-day session in the same week. In addition to two consumer trainers employed by the project, trainers were sourced from clinical services for the clinical sessions and the community sector for the community sessions. This was anticipated as enabling the inclusion of specialist skills and experience in the delivery of training.

Training in the second round was subject to further modifications based on analyses of evaluations of the first round of training by both participants and trainers. The delivery of the intervention was modified to account for previously unknown restrictions on the ability of services to release staff for two days of training. Based on feedback from services, it was identified that attending two days of training for some teams was difficult. This was either due to the workload of the teams (specifically CAT teams) or the recent undertaking of organisational wide recovery training (Ermha). In response to this the training was re-designed so that all material is covered in the first day of training, with more in-depth exploration and practice of the knowledge and skill on day two.

Feedback from the first round of training both through the structured feedback following training and from qualitative work led us to make several other modifications:

Training was restructured to allow half of the two days of training to be combined between the MHCSS sector and MH Staff. Feedback highlighted how the consumer role in leading training could be experienced as very challenging for some participants particularly if the consumer was experienced as critical of staff. Of course, being open to hearing criticisms from consumers about mental health care is a critical part of any transition to recovery-oriented practice so the training team worked very hard at considering this feedback in subsequent rounds. A key learning was that the introduction of the REACH coaching process needed to be deeply experiential. In particular, the training team formed the view that a critical element of the delivery was that the co-trainers as consumers and clinicians of other workers needed to embody the coaching principles in a fully

Commented [FS23]: I understood that the coaching training was more intensive and we brought in additional specialised expertise – Richard – so should this be further detailed?

authentic way. In alignment with a PDSA approach we took this on board as much as we could and adjusted the interactive style of the trainers for the second round. Additions to the PULSAR Manual included sections providing information on Advance statements, Nominated persons and Risk and Recovery with additional references. Additional material was provided in Appendix 2 and the title changed from "Additional resources for understanding values" to "Additional resources for consumers experiences". Additional web resources were added to Appendix 7 and the title changed changed from "Example of a relapse symptoms checklist" to "Care plans, and example of a relapse symptom checklist and other resources".

Commented [FS24]: From MIRF report

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Appendix 2

Perceived need for care findings

Instrumentation

The Perceived Need for Care Questionnaire is an interviewer administered questionnaire that in the form here used classifies seven forms of need:

1. Information about mental illness, its treatments and available services. (Information)
2. Medicine or tablets. (Medicines)
3. Counselling or talking therapy. (Counselling)
4. Practical issues such as housing or money issues. (Practical)
5. Help to improve the ability to work or use time in other ways. (Time use)
6. Help to improve the ability to look after themselves in their home. (Self-care)
7. Help to meet people for support and company (Company)

Through a branching conversationally styled questionnaire structure these needs are identified as judged by the participant to fall into four perceived need categories: no need, unmet need, partially met need, or met need.

Hypotheses

Here we examine three hypotheses, H1-H3: H 1: People in intervention as an outcome of more comprehensive assessment would identify more needs: H 2: People in intervention would be more likely to identify needs where present as met and less likely to identify them as unmet. H 3: H 2 would apply especially in more personal recovery than clinical goals areas, so here items 4-7.

Results

Table 8 Need Categories assessed with the Perceived Need for Care Questionnaire as associated with intrervention stat

Perceived Need category		PULSAR-REFOCUS Intervention status	No need (a)	Unmet need (b)	Partially met need (c)	Met need (d)	Proportion of all needs met (d/(b+c+d)	Proportion of all needs unmet b/(b+c+d)
1	Information	Control	22	14	35	66	57.4%	12%
		Intervention	10	23	26	66	57.4%	20%
2	Medicines	Control	6	0	26	105	80.2%	0%
		Intervention	2	4	17	100	82.6%	3%
3	Counselling	Control	11	13	38	75	59.5%	10%
		Intervention	11	12	41	61	53.5%	11%
4	Practical	Control	50	35	18	34	39.1%	40%
		Intervention	42	32	15	41	46.6%	36%
5	Time use	Control	48	38	14	35	40.2%	44%
		Intervention	41	31	13	42	48.8%	36%
6	Self-care	Control	56	32	13	38	45.8%	39%
		Intervention	42	29	13	42	50.0%	35%
7	Company	Control	38	34	16	46	47.9%	35%
		Intervention	37	26	23	39	44.3%	30%

Here, given the categorical nature of the data, smaller sample sizes than for primary outcome variables, and without expectation of this part of the study being fully powered, we have kept statistical analyses very simple.

H 1 - People in intervention as an outcome of better assessment would identify more needs: Here we find people in the in intervention group identified a perceived need in 696 of 881 invitations to do so 79%) while among control participants this proportion was 725/956 or 76%. A two sample test of proportions result gives a z-statistic = -1.54, p=0.0622, so in the marginal significance range of 0.05-0.10.
H 2 - People in intervention would be more likely to identify needs where present as met and less likely to identify these as unmet. Here, comparisons favour the intervention 8:5 with one tie. In 13 items, 8 favouring the intervention will occur by chance with a probability of 0.157 i.e. p=0.157 so here the probability of type I error in relation to the proposition that more needs will be identified in intervention group participants is 0.157 (here p>0.10 NS).
H 3: H 2 would apply especially in more personal recovery than clinical goals areas, so here items 4-7. Here comparisons favour the intervention 7:1. In 8 items, 7 favouring the intervention will occur by chance with a probability of 0.031. So here the p-value is 0.031 ie probability of type I error is 0.031 (here p< 0.05).

Conclusion

While noting the limitations of the analyses, two of the three hypotheses receive some support, one with $p<0.05$ and another with $0.05 < p < 0.1$ while the third is favoured in terms of direction of findings, though not significantly so. Considered in the context of the overall set of measures we would rate the PNCQ findings as overall favourable for the intervention condition over controls.

Appendix 3 – Model building for the stream 1 models of the QPR

Model 1.1 Stream 1 QPR mixed model with fixed factors of timepoint and intervention status, and clusters as random. Number of obs=942.

*** p<0.01, ** p<0.05, * p<0.1

		b	se	z	pvalue	ll	ul
Timepoint							
	T1	-3.59	1.13	-3.17	.002***	-5.81	-1.37
	T2	-4.78	1.60	-2.99	.003***	-7.92	-1.65
Intervention status							
	yes	4.15	1.54	2.69	.007***	1.13	7.18

Model Adjusted QPR means

		Model adj. QPR mean	Std.Err.	[95%Conf.	Interval]
Timepoint					
	T0	57.14	1.25	54.70	59.58
	T1	53.55	1.34	50.92	56.18
	T2	52.35	1.39	49.63	55.07
Intervention status*					
	0	52.25	1.46	49.37	55.12
	1	56.40	1.25	53.95	58.84

*The mean difference between treatment and control groups was 4·2 (95% Confidence interval: 1·1 – 7·2).

Model 1.2. Stream 1 QPR mixed model with fixed factors of sex, age-group, time and intervention status and clusters as random. Number of obs= 942

*** p<0.01, ** p<0.05, * p<0.1

		b	se	z	pvalue	ll	ul
sex							
	Female	-.86	1.05	-0.82	0.414	-2.92	1.20
Age group							
	2	-.88	.86	-1.02	0.308	-2.56	0.81
	3	-3.40	.93	-3.67	0.001***	-5.21	-1.58
Timepoint							
	T1	-3.20	1.07	-2.99	0.003***	-5.29	-1.11
	T2	-4.19	1.56	-2.69	0.007***	-7.25	-1.14
Intervention status							
	yes	3.74	1.56	2.36	0.018**	.63	6.85

Model adjusted QPR means

		QPR mean	Std.Err.	[95%Conf.	Interval]
sex					
	Male	54.82	1.29	52.29	57.35
	Female	53.96	1.25	51.51	56.41
age_cat					
	1	55.60	1.12	53.40	57.80
	2	54.72	1.22	52.34	57.10
	3	52.20	1.50	49.26	55.15
Timepoint					
	0	56.82	1.18	54.52	59.13
	1	53.63	1.38	50.93	56.33
	2	52.63	1.47	49.74	55.52
Intervention status*					
	0	52.47	1.53	49.46	55.47
	1	56.20	1.25	53.75	58.66

*The mean difference between treatment and control groups was 3·7 (95% Confidence interval: 0.7 – 6·8).

Model 1.3. Stream 1 QPR mixed model with fixed factors of sector, sex, age-group, time and intervention status, and clusters as random. Number of obs=942
*** p<0.01, ** p<0.05, * p<0.1

		b	se	z	pvalue	ll	ul
sex							
	Female	-0.818	1.05	-.78	.434	-2.87	1.23
Age group							
	2	-0.93	0.85	-1.09	.274	-2.59	0.74
	3	-3.43	0.91	-3.77	0.001***	-5.21	-1.65
Timepoint							
	T1	-3.20	1.07	-2.99	.003***	-5.30	-1.10
	T2	-4.18	1.56	-2.67	.008***	-7.24	-1.11
Intervention status							
	yes	3.72	1.64	2.27	.023**	0.51	6.92
Sector							
	2	-1.71	2.12	-0.81	.418	-5.87	2.44

Model adjusted QPR means

		QPR mean	Std.Err.	[95%Conf.	Interval]
sex					
	1	54.85	1.35	52.20	57.49
	2	54.03	1.22	51.63	56.42
age_cat					
	1	55.68	1.13	53.46	57.90
	2	54.75	1.24	52.31	57.19
	3	52.25	1.48	49.35	55.15
Timepoint					
	0	56.87	1.203	54.51	59.23
	1	53.67	1.42	50.885	56.45
	2	52.69	1.44	49.87	55.51
Intervention status					
	0	52.53	1.57	49.45	55.60
	1	56.24	1.26	53.77	58.72
sector					
	1	55.04	1.74	51.63	58.45
	2	53.39	1.23	50.91	55.75

*The mean difference between treatment and control groups was 3·7 (95% Confidence interval: 0.5 – 6·9).

Model 1.4. Stream 1 QPR mixed model with fixed factors of sector, step-group, sex, age-group, time and intervention status, and clusters as random. Number of obs=942
*** p<0.01, ** p<0.05, * p<0.1

		b	se	z	pvalue	ll	ul
sex							
	Female	-0.81	1.04	-0.79	.431	-2.84	1.21
Age group							
	2	-0.94	0.88	-1.07	.285	-2.65	0.78
	3	-3.4	0.91	-3.78	0.001***	-5.22	-1.66
Timepoint							

		b	se	z	pvalue	ll	ul
	T1	-3.22	1.02	-3.16	.002***	-5.22	-1.22
	T2	-4.22	1.50	-2.82	.005***	-7.15	-1.29
Intervention status							
	yes	3.76	1.31	2.87	.004***	1.20	6.33
Sector							
	2	-1.72	2.12	-0.81	.418	-5.87	2.43
Step group							
	2	0.15	2.08	0.07	.943	-3.93	4.22

Model adjusted QPR means

		QPR mean	Std.Err.	[95%Conf.	Interval]
sex					
	1	54.85	1.36	52.18	57.51
	2	54.03	1.23	51.63	56.44
age_cat					
	1	55.69	1.17	53.39	57.99
	2	54.75	1.25	52.31	57.20
	3	52.25	1.48	49.34	55.16
Timepoint					
	0	56.89	1.25	54.45	59.34
	1	53.67	1.43	50.86	56.48
	2	52.67	1.38	49.97	55.37
Intervention status					
	0	52.51	1.46	49.65	55.37
	1	56.27	1.23	53.87	58.67
sector					
	1	55.05	1.75	51.62	58.47
	2	53.33	1.24	50.91	55.75
step					
	1	54.29	1.42	51.52	57.07
	2	54.44	1.69	51.12	57.76

*The mean difference between treatment and control groups was 3·7 (95% Confidence interval: 0.5 – 6·8).

Appendix 4 – Interactions terms and stream 1 models of the QPR

Model 1.5. Stream 1 QPR (same as Tables 3A and 4A in original submission). Number of obs=942

Model 5 has interaction item of time and intervention status.

Time point	Intervention	Coefficient	Robust Std Err.	P>|z|	95% CI	
T0	No	3·59	1·13	0·002	1·37	5·81
T1	No	Reference				
T1	Yes	4·15	1·54	0·007	1·13	7·18
T2	Yes	2·96	1·39	0·030	0·24	5·68

Model adjusted QPR means

Time Point	Intervention	QPR raw data mean	QPR mean	95% CI	
T0	No	54·7	55·1	52·7	57·5
T1	No	51·5	51·5*	48·2	54·8
	Yes	55·3	55·6*	52·9	58·4
T2	Yes	53·9	54·4	52·1	56·8

*The mean difference between treatment and control groups at year 1 was 4·2 (95% Confidence interval: 1·1 – 7·2).

Model 1.6. Stream 1 QPR (same as Tables 3B and 4B in original submission). Number of obs=942

Model 6 has interaction item of time and intervention status, and fixed variables of age-group (<30; 30-49; 50 years and over) and sex (Male/Female)

		Coefficient	Robust Std Err.	P>|z|	95% CI	
Sex						
	Male			Reference		
	Female	-0·86	1·05	0·41	-2·92	1·20
Age Category						
	17-29			Reference		
	30-49	-0·88	0·86	0·31	-2·56	0·81
	50-75	-3·39	0·92	<0·001	-5·21	-1·58
Time point	**Intervention**					
T0	No	3·20	1·07	0·003	1·10	5·29
T1	No			Reference		
T1	Yes	3·74	1·59	0·02	0·63	6·85
T2	Yes	2·74	1·35	0·04	0·09	5·34

Model adjusted QPR means

Time Point	Intervention	QPR raw data mean	QPR mean	95% CI	
T0	No	54·7	55·0	52·6	57·3
T1	No	51·5	51·8*	48·4	55·2
	Yes	55·3	55·5*	52·7	58·3
T2	Yes	53·9	54·5	52·1	56·9

* The mean difference between treatment and control groups at year 1 was 3·7 (95% Confidence interval: 0·6 – 6·8).

Model 1.7. Stream 1 QPR (same as Tables 3C and 4C in original submission). Number of obs=942

Model has same variables as Model 6 plus sector (PMHS; MHCSS) as fixed.

	Coefficient	Robust Std Err.	P>|z|	95% CI
Sex				

		Male (reference)					
		Female	-0·76	1·05	0·47	-2·81	1·29
Age Category							
		17-29 (reference)					
		30-49	-0·90	0·84	0·28	-2·55	0·75
		50-75	-3·37	0·91	0·00	-5·15	-1·59
Time point	**Intervention**	**Sector**					
T0	No	**PMHS**	3·56	1·47	0·02	0·68	6·43
T0	No	**MHCSS**	2·58	2·65	0·33	-2·61	7·78
T1	No	**PMHS**	(reference)				
T1	No	**MHCSS**	0·03	3·23	0·99	-6·30	6·35
T1	Yes	**PMHS**	3·99	2·23	0·07	-0·38	8·37
T1	Yes	**MHCSS**	3·33	2·64	0·31	-1·85	8·51
T2	Yes	**PMHS**	4·30	1·85	0·02	0·67	7·93
T2	Yes	**MHCSS**	0·32	2·89	0·91	-5·35	5·98

Model adjusted QPR means

Sector	**Time Point**	**Intervention**	**QPR raw data mean**	**QPR mean**	**95% CI**	
PMHS	T0	No	55·0	55·4	51·6	59·2
	T1	No	51·1	51·8	47·0	56·7
		Yes	55·4	55·8	51·4	60·2
	T2	Yes	55·1	56·1	53·0	59·2
MHCSS	T0	No	54·3	54·4	52·6	56·3
	T1	No	52·3	51·9	47·8	55·9
		Yes	54·8	55·2	53·3	57·1
	T2	Yes	52·1	52·2	49·2	55·1

Model 1.8. Stream 1 QPR (same as Tables 3D and 4D in original submission). Number of obs=942

Model has same variables as model 7 plus 'step' group as fixed variable. Model also examined interactions between four variables (sector, step, time and intervention).

				Coefficient	**Robust Std Err.**	**P>|z|**	**95% CI**	
Sex								
			Male (reference)					
			Female	-0·76	1·06	0·47	-2·85	1·32
Age Category								
			17-29 (reference)					
			30-49	-0·87	0·87	0·32	-2·56	0·83
			50-75	-3·37	0·94	0·00	-5·22	-1·52
Time point	**Intervention**	**Step Group**	**Sector**					
T0	No	1	PMHSPMHS	5·83	3·40	0·09	-0·84	12·49
T0	No	2	PMHS	2·36	1·50	0·12	-0·58	5·30
T1	No	2	PMHS	(reference)				
T1	Yes	1	PMHS	5·02	4·21	0·23	-3·23	13·27
T2	Yes	1	PMHS	4·48	4·37	0·31	-4·09	13·04
T2	Yes	2	PMHS	4·92	1·65	0·00	1·68	8·16
T0	No	1	MHCSS	1·99	3·32	0·55	-4·52	8·50
T0	No	2	MHCSS	4·14	3·39	0·22	-2·50	10·78
T1	No	2	MHCSS	1·29	4·11	0·76	-6·77	9·34
T1	Yes	1	MHCSS	3·11	3·23	0·34	-3·22	9·43
T2	Yes	1	MHCSS	-0·29	3·16	0·93	-6·47	5·90
T2	Yes	2	MHCSS	1·94	4·20	0·65	-6·29	10·17

Model adjusted QPR means								
Sector	**Time Point**	**Step group**	**Intervention**	**QPR raw data mean**	**QPR mean**	**95% CI**		**Pre/post intervention diff. *Significant**
PMHS	T0	1	*No*	*57·1*	*57·2*	*54·6*	*59·7*	
	T1	1	Yes	55·4	56·4	50·9	61·8	-0·8 (z-score=0·5, p=0·64)
	T2	1	Yes	54·8	55·8	49·9	61·7	
PMHS	T0	2	*No*	*53·0*	*53·7*	*47·3*	*60·1*	
	T1	2	*No*	*51·1*	*51·3*	*45·2*	*57·5*	
	T2	2	Yes	55·4	56·2	53·0	59·5	4·9 (z-score=3·0, p=0·003)*

MHCSS	T0	1	*No*	*53·3*	*53·3*	*51·0*	*55·6*	
	T1	1	Yes	54·8	54·4	52·7	56·2	1·1 (z-score=2·7, p=0·006)*
	T2	1	Yes	51·3	51·0	50·0	52·0	
MHCSS	T0	2	*No*	*55·1*	*55·5*	*53·0*	*58·0*	
	T1	2	*No*	*52·3*	*52·6*	*47·4*	*57·8*	
	T2	2	Yes	52·7	53·2	47·8	58·7	0·7 (z-score=1·22, p=0·22)

Appendix 5 –Stream 2 models of the QPR

Model 2.1 Stream 2 QPR mixed model with fixed factors of time and intervention status, and clusters as random. Number of obs=269

	b	se	z	pvalue	[95%Conf.	Interval]
Timepoint						
T1	-0.50	2.79	-0.18	0.86	-5.95	4.96
T2	-2.74	3.94	-0.70	0.49	-10.45	4.98
Intervention status						
1	2.446	2.90	0.84	0.40	-3.23	8.12

Model Adjusted QPR means

	QPR mean	Std.Err.	[95%Conf.	Interval]
Timepoint				
T0	54.50	1.44	51.68	57.31
T1	54.00	1.47	51.12	56.88
T2	51.76	2.77	46.33	57.18
Intervention status				
0	52.34	2.29	47.84	56.83
1	54.78	0.93	52.96	56.60

Model 2.2 Stream 2 QPR mixed model with fixed factors of sex, age-group, time and intervention status, and clusters as random. Number of obs=265

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	-2.66	1.82	-1.47	0.143	-6.22	0.90
Age group						
30-49 years	0.98	1.79	0.55	0.585	-2.53	4.49
50 years and over	-3.01	2.11	-1.43	0.153	-7.14	1.12
Timepoint						
T1	-0.88	2.75	-0.32	0.749	-6.26	4.51
T2	-2.64	3.93	-0.67	0.502	-10.34	5.06
Intervention status						
1	2.52	2.74	0.92	0.356	-2.84	7.88

Model Adjusted QPR means

	Margin	Std.Err.	[95%Conf.	Interval]
Sex				
Male	55.00	0.83	53.34	56.61
Female	52.32	1.65	49.08	55.56
Age group				
17-30 years	53.84	1.64	50.62	57.07
30-49 years	54.82	1.18	52.51	57.13
50 years and over	50.83	1.61	47.68	53.99
Timepoint				
T0	54.60	1.39	51.88	57.34
T1	53.72	1.51	50.76	56.68
T2	51.96	2.79	46.49	57.43
Intervention status or sector				
0	52.25	2.18	47.97	56.54
1	54.78	0.96	52.90	56.65

Model 2.3 Stream 2 QPR mixed model with fixed factors of sector, sex, age-group, time and intervention status, and clusters as random. Number of obs=265

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	-2.68	1.94	-1.38	.168	-6.49	1.13
Age group						
30-49 years	.99	1.78	.55	.58	-2.50	4.48
50 years and over	-2.99	2.13	-1.41	.16	-7.16	1.18
Timepoint						
T1	-.88	2.80	-.32	.75	-6.37	4.61
T2	-2.67	4.15	-.64	.52	-10.81	5.47
Intervention status						
1	2.54	2.88	.88	.37	-3.09	8.18
Sector						
2	.23	2.07	.11	.91	-3.83	4.28

Model Adjusted QPR means

	QPR mean	Std.Err.	[95%Conf.	Interval]
sex				
Male	55.00	.81	53.40	56.57
Female	52.31	1.74	49.00	55.71
Age group				
17-30 years	53.83	1.67	50.55	57.11
30-49 years	54.82	1.20	52.47	57.17
50 years and over	50.84	1.59	47.73	53.95
Timepoint				
T0	54.61	1.45	51.77	57.45
T1	53.73	1.49	50.81	56.64
T2	52.00	3.00	46.19	57.60
Intervention status				
0	52.24	2.27	48.00	56.69
1	54.79	.97	53.00	56.70
sector				
1	53.38	1.82	49.81	57.00
2	53.61	.67	53.00	54.92

Model 2.4 Stream 2 QPR mixed model with fixed factors of sector, step-group, sex, age-group, time and intervention status, and clusters as random. Number of obs=265

Step variable omitted due to collinearity == model the same as 2.3

Appendix 6 –Stream 2 models of the secondary outcomes

Model 3.1 Stream 2 Warrick mixed model with fixed factors of time and intervention status, and clusters as random. Number of obs=272

	b	se	z	pvalue	[95%Conf.	Interval]
Timepoint						
T1	-.94	2.26	-.41	.68	-5.37	3.50
T2	-1.84	3.85	-.48	.63	-9.39	5.71
Intervention status						
1	1.99	2.42	.82	.41	-2.76	6.74

Model Adjusted means

	Warrick mean	Std.Err.	[95%Conf.	Interval]
Timepoint				
T0	42.84	1.40	40.08	45.59
T1	41.89729	1.22	39.50	44.30
T2	41.00	2.77	35.57	46.43
Intervention status				
0	40.92	1.97	37.07	44.78
1	42.91	.99	40.97	44.85

Model 3.2 Stream 2 Warrick mixed model with fixed factors of sex, age-group, time and intervention status, and clusters as random. Number of obs=268

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	-2.08	1.271	-1.64	.10	-4.57	.41
Age group						
30-49 years	.80	1.14	.71	.48	-1.43	3.03
50 years and over	-.32	1.13	-.28	.78	-2.53	1.89
Timepoint						
T1	-1.50	2.41	-.62	.53	-6.23	3.23
T2	-2.38	4.04	-.59	.56	-10.31	5.55
Intervention status						
1	2.36	2.48	.95	.34	-2.50	7.22

Model Adjusted means

	Warrick mean	Std.Err.	[95%Conf.	Interval]
sex				
Male	43.05	1.05	41.00	45.10
Female	40.97	1.28	38.47	43.47
age_cat				
17-30 years	41.58	1.43	38.77	44.39
30-49 years	42.38	1.21	40.01	44.76
50 years and over	41.26	1.02	39.26	43.26
Timepoint				
T0	43.23	1.51	40.27	46.18
T1	41.73	1.29	39.21	44.25
T2	40.85	2.84	35.282	46.42
Intervention status				
0	40.73	2.00	36.82	44.64
1	43.092	1.01	41.11	45.07

Model 3.3 Stream 2 Warrick mixed model with fixed factors of sector, sex, age-group, time and intervention status, and clusters as random. Number of obs=268

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	-2.1	1.33	-1.58	.11	-4.71	.51
Age group						
30-49 years	.815	1.13	.72	.47	-1.39	3.02
50 years and over	-.30	1.17	-.25	.80	-2.60	2.00
Timepoint						
T1	-1.51	2.46	-.61	.54	-6.33	3.31
T2	-2.42	4.15	-.58	.56	-10.55	5.72
Intervention status						
1	2.39	2.57	.93	.35	-2.66	7.43
Sector						
2	.33	2.03	.16	.87	-3.65	4.31

Model Adjusted means

	Warrick mean	Std.Err.	[95%Conf.	Interval]
sex				
Male	43.06	1.03	41.04	45.07
Female	40.96	1.32	38.37	43.54
age_cat				
17-30 years	41.57	1.46	38.72	44.41
30-49 years	42.38	1.22	39.99	44.78
50 years and over	41.27	1.02	39.28	43.26
Timepoint				
T0	43.24	1.55	40.21	46.28
T1	41.73	1.28	39.23	44.24
T2	40.82	2.90	35.14	46.51
Intervention status				
0	40.72	2.05	36.71	44.73
1	43.10	1.03	41.09	45.12
sector				
1	41.74	1.61	38.59	44.89
2	42.07	1.12	39.87	44.27

Model 3.4 Stream 2 Warrick mixed model with fixed factors of sector, step-group, sex, age-group, time and intervention status, and clusters as random. Number of obs=268

Step omitted due to collinearity == model the same as 3.3

Model 4.1 Stream 2 inspire_S_score mixed model with fixed factors of time and intervention status, and clusters as random. Number of obs=251

	b	se	z	pvalue	[95%Conf.	Interval]
Timepoint						
T1	-3.09	4.93	-.63	.53	-12.76	6.57
T2	-2.65	6.22	-.43	.67	-14.84	9.53
Intervention status						
1	1.23	5.45	.23	.82	-9.44	11.91

Model Adjusted means

	Inspire_S mean	Std.Err.	[95%Conf.	Interval]
Timepoint				
T0	64.47	3.64	57.33	71.61
T1	61.38	2.74	56.00	66.76
T2	61.82	3.10	55.74	67.90
Intervention status				
0	61.74	3.32	55.24	68.25
1	62.98	2.86	57.36	68.59

Model 4.2 Stream 2 inspire_S_score mixed model with fixed factors of sex, age-group, time and intervention status, and clusters as random. Number of obs=248

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	-2.61	3.19	-.819	.41	-8.86	3.64
Age group						
30-49 years	2.19	5.41	.40	.69	-8.41	12.78
50 years and over	1.30	4.89	.26	.79	-8.29	10.89
Timepoint						
T1	-3.79	4.67	-.81	.42	-12.94	5.36
T2	-3.01	6.06	-.50	.62	-14.89	8.86
Intervention status						
1	1.29	5.36	.24	.81	-9.21	11.80

Model Adjusted means

	Inspire_S mean	Std.Err.	[95%Conf.	Interval]
sex				
Male	63.88	2.64	58.72	69.05
Female	61.27	1.81	57.72	64.83
Age group				
17-30 years	60.97	4.26	52.62	69.31
30-49 years	63.15	2.30	58.65	67.66
50 years and over	62.26	2.10	58.15	66.38
Timepoint				
T0	64.90	3.53	57.99	71.83
T1	61.12	2.72	55.78	66.45
T2	61.89	3.07	55.88	67.90
Intervention status				
0	61.75	3.28	55.32	68.17
1	63.04	2.87	57.41	68.67

Model 4.3 Stream 2 inspire_S_score mixed model with fixed factors of sector, sex, age-group, time and intervention status, and clusters as random. Number of obs=248

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	-3.49	3.03	-1.15	.25	-9.43	2.46
Age group						
30-49 years	2.43	5.19	.47	.64	-7.74	12.61
50 years and over	1.63	4.82	.34	.73	-7.82	11.09
Timepoint						
T1	-4.34	3.44	-1.26	.207	-11.08	2.40
T2	-4.21	4.50	-.93	.35	-13.04	4.62
Intervention status						
1	2.03	4.46	.45	.65	-6.72	10.78
Sector						
2	7.55	2.50	3.02	.00	2.66	12.45

Model Adjusted means

	Inspire_S mean	Std.Err.	[95%Conf.	Interval]
sex				
Male	64.37	2.19	60.09	68.66
Female	60.89	1.68	57.60	64.17
age_cat				
17-30 years	60.74	4.02	52.86	68.63
30-49 years	63.18	2.09	59.24	67.11

Model Adjusted means

	Inspire_S mean	Std.Err.	[95%Conf.	Interval]
50 years and over	62.38	2.02	58.43	66.33
Timepoint				
T0	65.46	2.32	60.91	70.01
T1	61.12	2.34	56.53	65.71
T2	61.26	2.68	56.00	66.50
Intervention status				
0	61.37	2.54	56.40	66.35
1	63.40	2.51	58.47	68.33
sector				
1	59.01	1.21	56.65	61.38
2	66.57	2.19	62.27	70.86

Model 4.4 Stream 2 Inspire_R_score mixed model with fixed factors of sector, step-group, sex, age-group, time and intervention status, and clusters as random. Number of obs=268

Step omitted due to collinearity == model the same as 4.3

Model 5.1 Stream 2 inspire_R_score mixed model with fixed factors of time and intervention status, and clusters as random. Number of obs=263

	b	se	z	pvalue	[95%Conf.	Interval]
Timepoint						
T1	-1.72	4.09	-.42	.67	-9.74	6.30
T2	1.41	5.84	.24	.81	-10.04	12.86
Intervention status						
1	2.82	4.87	.58	.56	-6.72	12.36

Model Adjusted means

	Inspire_R mean	Std. Err.	[95%Conf.	Interval]
Timepoint				
T0	74.14	3.43	21.62	80.87
T1	72.43	2.44	29.70	77.21
T2	75.55	3.06	24.73	81.54
Intervention status				
0	72.31	2.75	26.27	77.71
1	75.14	2.89	25.99	80.80

Model 5.2 Stream 2 inspire_R_score mixed model with fixed factors of sex, age-group, time and intervention status, and clusters as random. Number of obs=259

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	.78	3.10	.25	.80	-5.30	6.86
Age group						
30-49 years	2.36	5.32	.44	.66	-8.06	12.78
50 years and over	4.26	5.45	.78	.43	-6.42	14.95
Timepoint						
T1	-2.02	4.19	-.48	.63	-10.22	6.19

T2	1.10	5.74	.19	.85	-10.16	12.36
Intervention status						
1	2.45	4.86	.50	.61	-7.07	11.97

Model Adjusted means

	Inspire_R mean	Std. Err.	[95%Conf.	Interval]
sex				
Male	73.27	2.30	68.77	77.76
Female	74.05	1.93	70.27	77.83
age_cat				
17-30 years	71.35	4.41	62.70	80.00
30-49 years	73.71	2.30	69.20	78.21
50 years and over	75.61	2.03	71.63	79.59
Timepoint				
T0	74.35	3.33	67.82	80.88
T1	72.33	2.44	67.54	77.12
T2	75.45	3.12	69.33	81.57
Intervention status				
0	72.49	2.84	66.91	78.06
1	74.94	2.79	69.47	80.40

Model 5.3 Stream 2 inspire_R_score mixed model with fixed factors of sector, sex, age-group, time and intervention status, and clusters as random. Number of obs=259

	b	se	z	pvalue	[95%Conf.	Interval]
sex						
Female	-.20	2.86	-.072	.94	-5.81	5.40
Age group						
30-49 years	2.47	4.89	.50	.61	-7.11	12.06
50 years and over	4.74	5.29	.90	.37	-5.63	15.1
Timepoint						
T1	-2.51	2.99	-.84	.40	-8.38	3.35
T2	-.44	3.43	-.13	.90	-7.16	6.27
Intervention status						
1	3.28	3.41	.96	.33	-3.39	9.97
Sector						
2	8.22	1.71	4.8	0	4.87	11.58

Model Adjusted means

	Inspire_R mean	Std. Err.	[95%Conf.	Interval]
sex				
Male	73.76	1.73	42.59	77.16
Female	73.56	1.62	45.40	76.73
Age group				
17-30 years	71.12	4.03	17.66	79.02
30-49 years	73.60	1.76	41.78	77.05
50 years and over	75.86	2.06	36.87	79.90
Timepoint				
T0	74.95	1.87	40.04	78.62
T1	72.44	1.75	41.42	75.87
T2	74.51	2.46	30.25	79.34
Intervention status				
0	72.04	1.97	36.65	75.89
1	75.33	1.86	40.45	78.98
sector				

Model Adjusted means

	Inspire_R mean	Std. Err.	[95%Conf.	Interval]
1	70.06	.98	71.53	71.99
2	78.29	1.47	53.12	81.18

Model 5.4 Stream 2 Inspire_R_score mixed model with fixed factors of sector, step-group, sex, age-group, time and intervention status, and clusters as random. Number of obs=259

Step omitted due to collinearity == model the same as 5.3

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