Lay health worker-delivered case management for early episodes of psychosis in Bangkok, Thailand (Lay-CARE): a single-centre, pragmatic, randomised controlled trial

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Summary

Background While specialist-led early intervention services (EIS) have been shown to be effective for early-phase psychosis, the effectiveness of a non-specialist-led EIS is still unclear. The study aims to determine the effectiveness of a low-intensity case management (LICM) programme led by lay health workers for patients during early episodes of psychosis on six-month outcomes compared to usual care (UC) in Bangkok, Thailand.

Methods This pragmatic randomised controlled trial (Lay-CARE) included patients aged ≥18 years with a history of a first or second episode of psychotic disorder residing in the Bangkok Metropolitan Region (Thammasat University hospital's catchment district). Participants were randomised to either LICM or UC group. LICM intervention consisted of family psychoeducation, facilitation of access to services, and home or telephone visits, whereas UC was the baseline of care participants were receiving. The intervention started in October 2020 and ended in May 2021. The 6-month endline assessment started in April 2021 and ended in May 2021. The primary outcome was social functioning measured by the Personal and Social Performance Scale Thai version. Secondary outcomes were symptom severity, service use and medication adherence. The treatment effect size was determined using the average treatment effect (ATE). Due to the nature of the intervention, blinding of participants and assessors was not possible. The trial was registered with the Thai Clinical Trial Registry (TCTR20210509001).

Findings 130 participants were randomised to LICM group and 125 to UC group. At the six-month endline, participants in LICM group demonstrated improved socially useful activities (ATE 0.06, 95% CI 0.00–0.13, $p = 0.041$), less aggressive or disturbing behaviour (ATE −0.17, 95% CI −0.27 to −0.06, $p = 0.002$), and better self-care (ATE 0.13 95% CI 0.05–0.22, $p = 0.003$) than participants in UC group. LICM intervention did not affect personal and social relationships, symptom severity, medication adherence, or service use.

Interpretation In low-resource settings, LICM programme can improve areas of social functioning among patients with early episodes of psychosis over six months.

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Keywords: Community health workers; Early intervention; Low and middle-income countries; Psychosocial intervention; Task-sharing

Introduction

Schizophrenia-spectrum disorders impose a substantial disease burden globally.[1] Left untreated or inadequately treated, the resulting economic percussions can be huge, with increased healthcare costs, productivity losses, and heightened demands on social support systems.[2]

Research in high-income countries has shown that early intervention services (EIS) led by specialists for psychotic disorders can result in better outcomes for individuals experiencing an early stage of psychotic illness, compared to usual care,[3] and could result in a better long-term trajectory.[4] These services typically involve early detection of untreated cases, evidence-

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Research in context

Evidence before this study

We searched the PubMed database from the first record to Dec 31, 2024, and using MeSH terms and the following keywords: "randomized controlled trial", "systematic review", "meta-analysis", "psychotherapy", "community mental health", "psychosocial intervention", "community-based intervention", "psychosocial support", "psychoeducation", "adherence support", "family support", "rehabilitation", "counselling", "community-based care", "case management", "continuity of patient care", "early intervention", "community health worker", "lay health worker", "non-specialist", "psychotic disorders", "early psychosis", "first episode psychosis", "early-stage psychosis", "psychosis" and "schizophrenia". We found no studies in either high-income countries (HICs) or low- and middle-income countries (LMICs) that employed lay health workers (LHWs) or community health workers (CHWs) to deliver early intervention services. We reviewed a systematic review on intensive case management (ICM) for severe mental ill health, as well as four systematic reviews on community-based psychosocial interventions for schizophrenia and other serious mental ill health. One of these reviews focused on studies in LMICs. ICM was found to be effective in improving several outcomes, including social functioning, particularly when compared to usual care in low-resource settings. There were no studies comparing less intensive case management with standard care. The findings on the effectiveness on community-based psychosocial interventions, regardless of being delivered by specialists or non-specialists, varied, but generally suggest that the interventions are effective. We also reviewed two systematic reviews of early intervention services (EIS) for early-phase psychosis, which suggest that EIS is generally effective in improving outcomes during the treatment period, but all EIS models in these studies were led by specialists and delivered in HICs.

Added value of this study

To our knowledge, this is the first trial of a lay worker-led case management-based care to improve outcomes for patients experiencing an early episode of psychosis. In low-resource settings where usual care is limited, this less intensive approach may be effective in enhancing social functioning within the context of early intervention services.

Implications of all the available evidence

Targeting collaborative case management toward individuals with early-stage psychosis and integrating it into the existing community-based work of lay health workers may offer a more cost-effective strategy than focusing on those with chronic or multiple-episode mental illness. Further investigation in diverse settings and with longer follow-up periods is needed to confirm and extend these findings.

based care and case management.[5,6] However, due to their emphasis on high-intensity input and delivery by specialists, EIS can be challenging to implement at scale, even in high-income countries.[7]

In low- and middle-income countries (LMICs), it may not be feasible to establish specialised EIS when even basic care for psychotic disorders is lacking. One potential solution is to utilise non-specialist health workers to adapt and deliver core components of mental health services,[8] a strategy supported by evidence of its feasibility in LMICs.[9] This approach also aligns with the recommendations of the WHO's Mental Health Action Plan (2013–2030) and the World Psychiatric Association (WPA), which propose that lay health workers (LHWs) should be essential members of a comprehensive mental health care team to improve areas of services[10] and to increase the accessibility of early intervention services in LMICs.[11]

It is increasingly popular that LHWs with relatively little formal training can provide direct and collaborative care to people with mental ill health,[12] address various practical and social needs, help overcome structural barriers to services, and potentially improve outcomes (Barnett et al., 2018). In Thailand, community-based LHWs, locally known as village health volunteers (VHVs), have played a crucial role in continuing care of people with chronic illnesses and physical disabilities through case management programmes.[13] However, evidence is lacking as to whether such LHW-led programmes can be adapted to deliver psychosocial interventions and improve outcomes of serious mental ill health, particularly within the context of early intervention service. Preliminary evidence from a quasi-experimental study on a newly developed low-intensity case management programme (LICM) showed that the model was feasible and promising.[14] Drawing on the study's intervention protocol and identified areas for improvement, we aimed to test the effectiveness of the LICM programme on 6-month outcomes using a pragmatic randomised controlled trial. We hypothesised that patients in an early stage of psychotic illness receiving LICM would have better social functioning, clinical and service outcomes than patients receiving usual care (UC) at six months.

Methods

Study participants

This single-centre, pragmatic, randomised controlled trial aimed to include a broad range of patients at an early stage of the illness, regardless of age group or onset. Eligibility was not restricted to young people with a recent onset (e.g. within the past few years prior to recruitment) but also extended to older individuals with recent or earlier onset. This broader eligibility was intended to enhance the study's generalisability to those experiencing an early episode of psychosis in the community population.

The study was conducted in Thammasat University hospital's catchment district north of the Bangkok Metropolitan Region (BMR). We recruited patients who were aged 18 years or older with a history of one or two episodes of psychosis, as determined by the Psychosis Section of the World Mental Health Survey-Composite International Diagnostic Interview (WMH-CIDI),[15] Eligible participants had participated in the LICM program development phase over a year earlier.[14] However, only a small subset of the participants had received the LICM intervention during the earlier phase. Specifically, of the 549 participants in the that phase, only 26 had received LICM and met the inclusion criteria for the current trial. These participants were then randomly allocated to either the intervention or control arm. The remaining 229 eligible participants in the current trial had never received LICM. Given the one-year gap between phases, the modest effects of LICM observed in the intervention development phase, and the small number of affected participants included in the current trial, any potential carryover or contamination effects were likely minimal. Patients with alcohol or illicit drug addiction were excluded from the study. Further details on the identification and screening process for potential eligible participants are provided elsewhere.[14] The study sample consisted of all remaining patients who had previously participated in the LICM program development study.[14] The sample size was not calculated for two primary reasons. First, there were no previous studies using a comparable intervention and methodology to guide sample size estimation (our previous study[14] had a different hypothesis). Second, budget constraints limited our ability to recruit additional participants. The study protocol is provided as Supplementary Information.

The suburban district, where the study was conducted, was undergoing rapid urbanisation and characterised by a mix of residential, industrial and commercial areas. As with mental health services across Thailand, patients in this study setting could seek care from various providers within or outside their catchment area and switch providers at any time. It was also common for patients to drop out of the system at some point.

Written informed consent was obtained from participants, where possible, or from the participant's parents or guardians for those without capacity to consent. The trial received approval from the Ethics Committee of Thammasat University (No 096/2560) on June 6, 2017, and was registered with the Thai Clinical Trial Registry (TCTR20210509001).

Interventions

Low-intensity case management (LICM) programme

LICM was built on the existing community-based case management platform led by LHWs for long-term physical care. The principal aim was to provide an outreach and coordinated approach that extended beyond routine facility-based mental health services to address the unmet needs of individuals with early-phase psychosis.

LICM had four major components, each supported by literature for its efficacy in improving psychosis outcomes.[16,17] Training on these LICM components has been part of a recent nationwide initiative to equip LHWs with the knowledge and skills needed to provide mental health care in the community. The training was primarily based on a series of mental health manuals,[18,19] developed by the Department of Mental Health (DMH) for primary and community health care workers (DMH is the national authority responsible for mental health policy and services). The manuals covered topics such as the roles of health workers in patient and caregiver mental health care, the rights of individuals with mental ill health, interviewing techniques, providing psychoeducation on psychotic disorders, antipsychotic medications and common adverse effects, various symptom and psychosocial functioning assessment forms, the referral system, and quizzes with answer keys.

(i) Home or telephone visits

These visits were designed to encourage continuity of care, provide psychoeducation and support, and address any emerging issues. They aimed to enhance the emotional well-being of patients and caregivers by listening for ongoing or new concerns and promoting adherence to treatment plans. Issues identified during the visits, including poor medication adherence, side effects, early signs of relapse, potentially disruptive behaviours, and financial barriers, were addressed promptly to enable timely adjustments to the treatment plan. While home visits were the primary means, telephone visits were used when home visits posed potential safety risks for LHWs, such as when dealing with cases with a history of violence or unpredictable behaviour. Telephone visits were also chosen when patients or caregivers felt more comfortable discussing mental health concerns over the phone. Patients could receive either type of visit or a combination of both during the intervention period. Visits were conducted weekly, fortnightly or monthly depending on the patient's needs. Additional visits were provided upon request in case participants were deemed unstable. Each visit typically lasted 30–60 min.

(ii) Family psychoeducation

This component focused on improving the families' understanding of the illness, fostering a caring attitude towards the patients, and preventing relapse. It was primarily delivered to patients' caregivers during home or telephone visits, equipping them with the knowledge and skills needed to support the patient. LHWs provided psychoeducation based on their training and accompanying manuals, tailoring the content to the family's specific concerns, the patient's symptoms, and treatment needs. They also offered guidance on appropriate actions to take, and techniques for using supportive communication with the patient.

(iii) Facilitation and navigation of access to health and social services

This component included assisting patients in accessing universal health coverage and disability benefit schemes, coordinating care across various services, giving appointment reminders, covering transportation costs, and, when necessary, accompanying patients to care facilities.

(iv) Crisis intervention

This was provided when an individual became disturbed, suicidal or aggressive, ensuring immediate support and appropriate management of the crisis.

Three sets of health workers coordinated the programme implementation. Their characteristics, roles and responsibilities were as follows:

(i) Facility-based mental health professionals (FMHs)

This team comprises three members: a consultant psychiatrist, a clinical psychologist, and a mental health nurse. They provided clinical leadership, supervision and advice on necessary pharmacological treatment and treatment planning through weekly meetings with FCMs. Any problems raised by the FCMs were discussed to make individualised decisions for each patient.

(ii) Facility-based case managers (FCMs)

These full-time LHWs (n = 2) had at least 12 years of schooling and strong interpersonal skills. They were recruited based on shared sociodemographic backgrounds with CCMs to serve as potential "opinion leaders" and a "bridge" between FMHs and CCMs, in line with the social network intervention techniques.[20] Trained in supervision and monitoring skills, FCMs provided direct support to CCMs, helping them to navigate the healthcare system, facilitate referrals, and ensure patients received timely access to necessary services. They supervised CCMs on the frequency and content of home visits to ensure fidelity and quality in the care delivery. FCMs conducted home or telephone visits for certain patients and caregivers who preferred them over CCMs (partly due to concerns about privacy related to mental health issues and care delivered by CCMs within the communities).

(iii) Community-based case managers (CCMs)

These part-time LHWs (n = 5) resided in the communities and had completed training required for long-term physical care. All CCMs had participated in the earlier LICM programme development study, giving them experience in delivering psychosocial interventions. CCMs and FCMs collaborated closely, exchanging information on patients' progress or changes in their condition to ensure coordinated and comprehensive care.

Usual care (UC)

Usual care referred to the baseline of care, which might include facility-based mental health services received by some participants during the study period, with no additional interventions provided by LHWs. A typical facility-based mental health service in Thailand follows a non-assertive approach, where patients and/or caregivers are responsible for proactively seeking care and scheduling follow-up appointments at the facility. There is usually no telephone or other means of follow-up for missed appointments if patients fail to attend. The frequency of contact depends on clinical need, mostly ranging from monthly to four-monthly. Mental health care facilities are generally led by psychiatrists, and the services are usually delivered in outpatient settings or through consultations, with initial appointments lasting up to about an hour for new patients and follow-up ones lasting 10–15 min or less, typically including prescribing antipsychotic medications and general information about psychotic illness. Patients and/or caregivers may choose to switch care to different mental health providers anytime, anywhere. Treatment dropout and nonadherence to medications are common in this model of care. Although a recent nationwide initiative by the DMH aimed to train LHWs to provide community-based continuity of care alongside the usual specialist-led facility-based services, most LHWs still lacked ongoing supervision and support from specialists, limiting the widespread availability of this community care model.

Measurement

Enrolment and baseline data collection were conducted from July 2020 to September 2020. The intervention started in October 2020 and ended in May 2021. The 6-month endline assessment started in April 2021 and ended in May 2021. FCMs made the assessments at both baseline and endline.

Primary outcome

Social functioning was measured by the Personal and Social Performance Scale (PSP),[21] Thai version.[22] Social functioning was chosen as the main outcome as it is more closely linked to recovery goals than clinical symptom reduction alone.[23] PSP assesses four primary domains of social functioning: socially useful activities; personal and social relationships; self-care; and disturbing and aggressive behaviours. The scale employs a six-point scale to assess difficulty in each domain, with lower ratings indicating better social functioning (1 = absent, 2 = mild, 3 = manifest, 4 = marked, 5 = severe, or 6 = very severe). The Thai version demonstrated moderate to good inter-rater reliability across the four domains, with intraclass correlation coefficients (95% CI) as follows: 0.63 (0.28–0.96) for socially useful activities, 0.75 (0.42–0.98) for personal and social relationships, 0.69 (0.35–0.97) for self-care, and 0.52 (0.17–0.94) for disturbing/aggressive behaviour.[22] PSP was initially designed to be administered by mental health professionals after a short training,[21] making it challenging for use in large-scale community-based studies. Because our focus centred on optimising the utility of PSP in settings where LHWs play a pivotal role, we needed to tailor the instrument for administration by lay interviewers. During instrument training and piloting, complexities and difficulties in rating the original PSP domains faced by the lay assessors were observed. This was primarily due to its response options being too closely aligned in meaning, a challenge that has also been reported in other studies.[24,25] We therefore condensed the original six-point scale for each domain into three categories: 1 = absent or mild, 2 = manifest or marked, and 3 = severe or very severe. Although this modification might reduce statistical power, it still preserved the scale's ability to distinguish between various levels of difficulty within each domain, and its influence on the interpretability and validity of the ratings was likely minimal.[26]

Secondary outcomes

Symptom severity was assessed with the Clinical Global Impression–Severity Scale (CGI-S).[27] CGI-S asks a single question: "*How mentally ill is the patient at this time?*", which is rated on the following seven-point scale, considering symptoms, behaviour, and function in the past seven days: 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill patients. In Thailand, community health workers have received training by DMH in its administration. The scale is included in one of DMH's community mental health care manuals,[18] which provides detailed guidelines on how to rate the scale. Although CGI-S was originally designed for use by health professionals, it has also been effectively employed by lay health workers.[28] While its psychometric properties in the context of lay health workers in Thailand have not yet been formally evaluated, its inclusion in national guidelines and widespread adoption in community care indicate its practical utility and acceptability in the local setting.

Service use was assessed with information provided by patients or caregivers, based on the Psychosis and Service Sections of the WMH-CIDI,[15] which detailed the regularity of outpatient visits, the number of inpatient admissions, and the number of emergency room (ER) visits for mental health reasons.

Medication adherence was assessed through multiple sources to ensure its reliability and accuracy. Emphasis was given to information from participants who were asked to self-report the regularity of their medication intake in the past 30 days at baseline and endline. Caregivers' reports were utilised as supplemented information and the most trusted source only when deemed more reliable (e.g. caregivers were actively involved in administering the medications) or when participants showed difficulties or uncertainties in accurately recalling their medication adherence (e.g. due to impaired cognitive functioning or impaired motivation, insight or self-care). Adherence was categorised as follows: (i) regular or mostly regular medication, (ii) fairly or mostly irregular medication, (iii) never treated or refused or already discontinued medication.

Covariate variables

The following covariates were assessed based on their predictions of potential long-term prognosis of psychotic disorders: age (continuous),[29] one-year history of illicit drug use,[30] age at onset of psychotic symptoms,[31] current psychotic symptoms,[29] and lifetime history of psychiatric admissions.[32]

Randomisation and masking

Participants were randomised to different arms following the method described by Pocock.[33] An independent assistant, blinded to participant identities, conducted the randomisation using computer-generated random numbers. Eligible participants were assigned to LICM or UC in a 1:1 ratio, using stratified balanced block randomisation in blocks of four. Stratification was based on age and sex. Baseline assessments were conducted by FCMs post-randomisation. However, allocation was concealed from them until the completion of baseline assessments. While blinding of assessors and participants to intervention allocation was not feasible. We implemented a number of strategies to minimise potential bias: (i) Blinding the study objectives and hypotheses–Both assessors and participants were unaware of the study hypotheses or objectives and only informed that the project aimed to engage patients in continuing treatment, (ii) Use of standardised assessment tools–Assessors used standardised, objective tools to ensure consistency and reduce subjective bias in assessments, (iii) Framing the project as service delivery–The project was presented as an opportunity to deliver community support rather than as a research study. It was emphasised that, due to limited resources, only a subset of patients—selected through randomisation–would receive the specified package of care, and that participants' conditions might fluctuate over time and, in some cases, may not show improvement despite the best efforts, given the chronic nature of the illness, (iv) Focus on unmet needs–FCMs were instructed to document patients' progress and remaining unmet needs rather than assess improvements, ensuring that their role remained focused on providing support and identifying ongoing challenges to facilitate further care if needed, and (v) Flexible care approach–The distinction between LICM and UC groups was not rigid, as care was tailored to individual needs. FCMs understood that participants in the UC group also received support, albeit in a different form, and intervened when necessary, helping to reduce differential expectations and potential bias.

Statistical analysis

Descriptive statistics were used to summarise the characteristics of study participants. Mean (SD) and frequency (percentage) were reported for continuous and categorical data, respectively. Baseline and endline outcome measures were presented by treatment group.

To estimate treatment effects of LICM, intention-to-treat analyses were performed to compare primary and secondary outcomes between the two groups at endline. Given the highly skewed distributions of outcome data and the very small numbers in certain response categories (i.e. severe or very severe) for many PSP domains and CGI-S (i.e. markedly or severely ill), these categories were combined with the adjacent ones to create a binary variable. Generally, when the dependent variable is binary, non-linear models are typically used. However, a linear regression model has also been utilised to directly calculate the treatment effects due to advantages over the non-linear regression approach.[34] We used this approach to calculate the average treatment effects (ATEs) by regressing the outcome variables, and robust standard errors by using the variance-covariance matrix of the estimators (vce). We also estimated potential outcome means (POMs), which represented the predicted means for the LICM group relative to the UC group. The analyses were adjusted for baseline covariates, including age, one-year history of illicit drug use, age at onset of psychotic symptoms, current psychotic symptoms, and lifetime history of psychiatric admissions. The observed ATE of LICM on an outcome, defined as the difference in proportions of the outcome (or absolute risk reduction) between the two study arms, were interpreted in terms of effect size based on Cohen's criteria.[35] Specifically, an ATE of 0.05–0.10 was considered a small effect, 0.10–0.20 a moderate effect, and 0.20–0.30 or greater a large effect. Statistical significance was set at the 5% level. Stata version 14.2[36] was used for all analyses. Analyses were performed by TJ.

Role of the funding source

The sponsor of the study had no role in study design, data collection, analysis, interpretation, or writing of the report.

Results

Sample description and baseline characteristics

Flow diagram of study enrolment, allocation, baseline and endline assessments was shown in CONSORT flowchart (Fig. 1). All in all, 343 out of a total of 549 patients had experienced one or two psychotic episodes and met eligibility for study inclusion. Among these, 49 had comorbid alcohol and substance use disorders and were excluded. After randomisation, 148 were assigned to LICM group and 146 to UC group. By the baseline assessment, 13 had moved out of the area and 5 deceased in the LICM group, leaving 130 in this arm. In the UC group, 12 had relocated and 9 deceased, leaving 125 assigned to the group.

In the LICM group, most agreed to receive home visits (n = 123). Only a few participants or caregivers in this group chose to receive telephone visits only (n = 7). However, during the intervention period, some caregivers of the UC group requested assistance due to worsening symptoms in the patients under their care. These patients were closely monitored and received certain components of the LICM programme involving home or telephone visits and referrals to outpatient or emergency services (n = 7).

Table 1 shows the baseline characteristics of the study sample by LICM and UC assignment. The sample was predominantly female (58.0%) with a mean age of 48.6 years. The majority completed primary school education or less (85.1%). More than 90% of the sample had a history of psychiatric treatment. Just below one-third (29.8%) had a lifetime history of psychiatric hospitalisation and around one-fifth (19.2%) reported current presence of active psychotic symptoms. Around 8.2% had a history of illicit drug use and just over half (55.3%) had the onset of psychosis before age 40. The majority had had regular outpatient visits in the previous year (77.7%) and reported good level of medication adherence (70.6%). Around 2.8% had presented to an emergency room and been hospitalised in the previous year. On PSP domains, more than half (58.4%) had severe or very severe limitations in socially useful activities, 0.4% had severe or very severe difficulties with personal and social relationships, 4.7% had poor or very poor self-care, and 2.4% had severe or very severe disturbing or aggressive behaviour.

The demographic and clinical characteristics were broadly similar between the two groups, except that, compared with the UC group, significantly higher proportions of the LICM group had severe or very severe difficulties in socially useful activities (61.5% vs

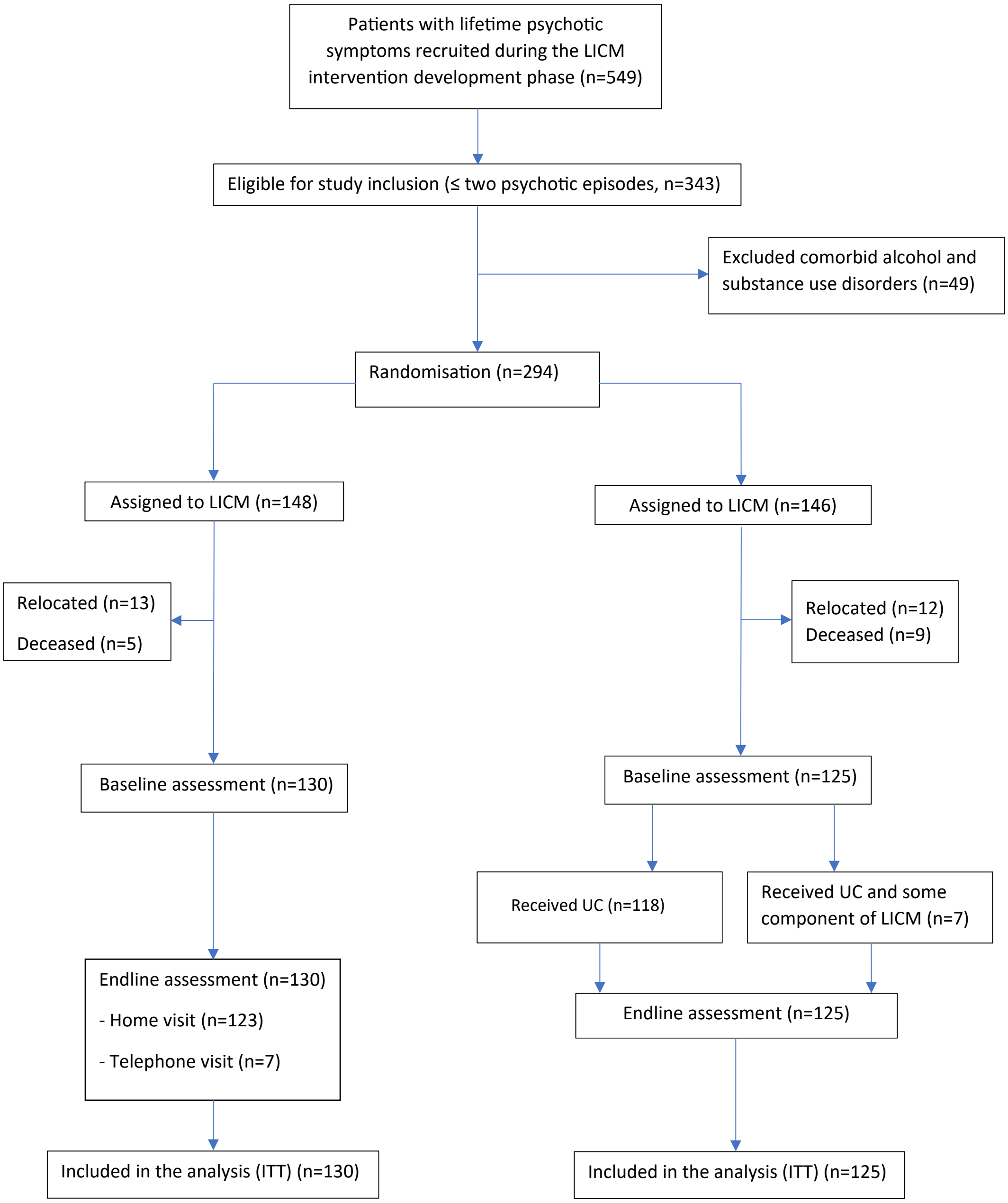

***Fig. 1:* Trial profile.** LICM: low-intensity case management programme, UC: Usual care, ITT: Intention-to-treat.

55.2%, p = 0.003) and personal and social relationship (0.8% vs 0.0%, p = 0.032).

Average treatment effects (ATEs) of LICM on outcomes

Table 2 displays the ATEs of LICM on primary and secondary outcomes controlled for baseline differences. At the endline, LICM showed better social functioning outcomes compared to usual care, specifically in socially useful activities (ATE 0.06, 95% CI 0.00–0.13, p = 0.041), self-care (ATE 0.13, 95% CI 0.05–0.22, p = 0.003), and disturbing or aggressive behaviour (ATE –0.17, 95% CI –0.27 to –0.06, p = 0.002). However, no significant effects were observed on personal and social relationships (ATE 0.01, 95% CI –0.02 to 0.05, p = 0.430) and symptom severity (ATE –0.03, 95% CI –0.15 to 0.09, p = 0.580). To aid interpretation, for socially useful activities, the estimated proportion of participants (adjusted for covariates) with absent or mild difficulty was 32% in the UC group (POM = 0.32)

Characteristics	Total (N = 255)		UC (N = 125)		LICM (N = 130)	
	N	%	N	%	N	%
Gender						
Male	107	42.0	53	42.4	54	41.5
Female	148	58.0	72	57.6	76	58.5
Age in years (mean, SD)	48.6 (15.4)		48.9 (15.4)		48.3 (15.6)	
Education						
≤Primary school	217	85.1	105	84.0	112	86.2
>Primary school	38	14.9	20	16.0	18	13.9
Current psychotic symptom severity						
None or borderline	206	80.8	103	82.4	103	79.2
Mild to severe	49	19.2	22	17.6	27	20.8
History of psychiatric hospitalisation						
No	179	70.2	88	70.4	91	70.0
Yes	76	29.8	37	29.6	39	30.0
Illicit drug use						
No	234	91.8	116	92.8	118	90.8
Yes	21	8.2	9	7.2	12	9.2
Age at onset of psychosis						
10–39 years	141	55.3	76	60.8	65	50.0
≥40 years	114	44.7	49	39.2	65	50.0
Regular outpatient follow-up visits in the previous year						
No	57	22.4	27	21.6	30	23.1
Yes	198	77.7	98	78.4	100	76.9
Level of adherence						
Fair or poor	75	29.4	24	27.2	41	31.5
Good	180	70.6	91	72.8	89	68.5
ER presentation in the previous year						
No	248	97.3	124	99.2	124	95.4
Yes	7	2.8	1	0.8	6	4.6
Previous year inpatient admission						
No	248	97.3	124	99.2	124	95.4
Yes	7	2.8	1	0.8	6	4.6
Difficulties in socially useful activities						
Absent or mild	86	33.7	52	41.6	24	26.2
Manifest or marked	20	7.8	4	3.2	16	12.3
Severe or very severe	149	58.4	69	55.2	80	61.5
Difficulties in personal and social relationships						
Absent or mild	233	91.4	120	96.0	113	86.9
Manifest or marked	21	8.2	5	4.0	16	12.3
Severe or very severe	1	0.4	0	0.0	1	0.8
Difficulties in self-care						
Absent or mild	145	56.9	79	63.2	66	50.8
Manifest or marked	98	38.4	42	33.6	56	43.1
Severe or very severe	12	4.7	4	3.2	8	6.2
Disturbing or aggressive behaviour						
Absent or mild	182	71.4	92	73.6	90	69.2
Manifest or marked	67	26.3	30	24.0	37	28.5
Severe or very severe	6	2.4	3	2.4	3	2.3

LICM: low-intensity case management programme, UC: Usual care, ER: Emergency room.

Table 1: **Baseline characteristics of patients randomised to LICM or UC.**

and 38% in the LICM group (POM = 0.38). This represents a modest improvement in socially useful activities in the LICM group, corresponding to a small effect size of 6% (ATE = 0.06). In terms of self-care, the estimated proportion of participants (adjusted) with absent or mild difficulty was 50% in the UC group (POM = 0.50) and 63% in the LICM group (POM = 0.63). This suggests a more substantial

Main outcome[a]	ATE			POM (95% CI)	
	Adjusted coefficient	95% CI	p value	UC	LICM
Socially useful activities	0.06	0.00–0.13	0.041	0.32 (0.27–0.37)	0.38 (0.34–0.42)
Personal and social relationships	0.01	−0.02 to 0.05	0.430	0.95 (0.92–0.99)	0.97 (0.95–0.99)
Self-care	0.13	0.05–0.22	0.003	0.50 (0.43–0.56)	0.63 (0.57–0.69)
Disturbing or aggressive behaviour	−0.17	−0.27 to −0.06	0.002	0.48 (0.40–0.56)	0.32 (0.25–0.39)
Symptom severity	−0.03	−0.15 to 0.09	0.580	0.67 (0.59–0.75)	0.64 (0.56–0.72)
Regular outpatient follow-up visit	0.04	−0.02 to 0.11	0.184	0.79 (0.75–0.83)	0.83 (0.78–0.88)
Inpatient admission	−0.02	−0.04 to 0.01	0.131	0.02 (−0.01 to 0.04)	−0.00 (−0.01 to 0.00)
Any psychiatric ER visit	−0.02	−0.05 to 0.01	0.119	0.02 (−0.00 to 0.04)	−0.00 (−0.01 to 0.00)
Medication adherence	0.03	−0.04 to 0.10	0.431	0.75 (0.70–0.80)	0.77 (0.72–0.82)

ATE: Average treatment effect; LICM: low-intensity case management programme; UC: Usual care; POM: Potential outcome mean; ER: Emergency room. [a]Values were adjusted for relevant unbalanced baseline values of each PSP domain and other baseline covariates (age, current presence of active psychosis, illicit drug use, age at onset of psychosis and history of inpatient admission).

Table 2: **ATEs of receiving LICM on outcomes on 6-month post-baseline using intention to treat analysis (n = 255).**

improvement in self-care for the LICM group, corresponding to a moderate effect size of 13% (ATE = 0.13). Overall, the number needed to treat (NNT) to improve at least one PSP domain was six.

It is worth noting that better social functioning outcomes in the LICM group did not necessarily indicate improvement post-intervention. Contrary to improvements observed in PSP domains of socially desirable activities and self-care, the domain of disturbing and aggressive behaviour had worsened in both the UC and LICM groups at the endline, although to a significantly greater degree in the UC group. Specifically, the proportion of individuals with absent or mild difficulties in this domain had substantially decreased from 73.6% to 52.8% in the UC group and slightly decreased from 69.2% to 66.9% in the LICM group (Supplementary Table S1).

Regarding service use, no statistically significant difference in regular outpatient visit was found between the two groups at six months (ATE 0.04, 95% CI −0.02 to 0.11, p = 0.184). No significant differences were observed in other areas including inpatient admissions (ATE −0.02, 95% CI −0.04 to 0.01, p = 0.131), emergency room visits (ATE −0.02, 95% CI −0.05 to 0.01, p = 0.119) and medication adherence (ATE 0.03, 95% CI −0.04 to 0.10, p = 0.431).

Discussion

This study highlights a novel treatment approach for individuals with a broader range of early psychotic episodes by involving facility-based and community-based lay health workers in delivering EIS within the case management platform. The findings show that LICM was more effective than UC on the psychosocial functioning domains of disturbing or aggressive behaviour, self-care and socially useful activities at the end of the 6-month intervention period.

The results also offer insights into the varying effects of LICM on different PSP outcome domains. While LICM demonstrated improvements in self-care and socially useful activities, it only mitigated the escalation of disturbing and aggressive behaviours, rather than preventing them. The underlying reason for this difference remains unclear. One possible explanation is that the UC group may have received insufficient social and psychoeducational support to handle interpersonal conflicts, such as those in families with high expressed emotion, which could trigger or exacerbate aggressive behaviours.[37] In contrast, those receiving LICM likely benefited form more comprehensive support in these areas. This highlights the complexities of psychosocial interventions, the multifaceted nature of behavioural change and the need for further investigation.

Regarding other outcomes, LICM did not lead to improvements in personal and social relationship and symptom severity. This could partly be explained by the fact that their baseline levels were already relatively good in both groups (Table 1). The proportions of individuals with no or mild difficulties in personal and social relationship problem were 86.9% in LICM and 96.0% in UC, and those with no active symptoms in LICM and UC were 79.2% and 82.4%, respectively. LICM therefore added no additional value in improving these outcomes.

In terms of service use, patients in the LICM group did not show improved regularity of outpatient visits, a reduction in unscheduled services (i.e. inpatient admissions and emergency department visits), or better medication adherence, similar to what was observed in symptom severity and the PSP domain of personal and social relationship. This may suggest a ceiling effect, where the initial high performance on these outcomes left little room for noticeable improvement.

To our knowledge, there have been no previous studies on evaluating the effectiveness of a similar kind of early intervention service led by non-specialists. Nevertheless, the study findings are generally in line with specialist-led EIS studies, which showed that these programmes generally provide better social functioning outcomes than usual care during the intervention period.[38]

The true active ingredients behind LICM's effectiveness remain debatable. although it is worth noting that, compared to LICM, UC only received a passive, low-intensity facility-based service, so augmenting this with LICM, which provided a variety of psychosocial support components would potentially improve outcomes. Notably, since the programme appeared to primarily enhance social functioning rather than other outcomes, two specific components, home or telephone visits and family psychoeducation, may have played a particularly critical role. Evidence from randomised controlled trials suggest that community-based programs involving home visits can improve engagement with patients and caregivers and improve aspects of social functioning.[39,40] Similarly, psychosocial interventions such as family psychoeducation can facilitate better understanding, reduce stigma, increase support and reduce levels of high expressed emotion, all of which can contribute to enhanced social functioning.[41,42] Longitudinal data also suggests that interventions that improve the level of social support for individuals with psychotic disorders in the early stages of treatment predicts longer term social functions independently of other characteristics.[43,44]

Although health specialists-led EIS services have been shown to yield most optimal outcomes, our study showed that less intensive EIS led by non-specialists can also create a positive impact on certain social functioning domains. Refining the work of collaborative case management for mental illness by targeting people with an early-stage psychotic illness and incorporating it into the existing community-based care work of LHWs could be a way forward. This might in turn offer potentially better cost-effectiveness outcomes than an approach focusing on individuals with a history of multiple episodes or chronic mental ill health.

The study has several strengths. The outreach nature of the LICM program makes the study sample more representative of the community patient population than those only recruited from a facility-based patient population. Naturally, the drop-out rate was very low in this community-based program, compared to facility-based EIS ones.

Several limitations should be considered when interpreting these findings. First, the potential for bias due to unblinding cannot be entirely ruled out, as FCMs were responsible for delivering the intervention and assessing outcomes, and the principal investigator conducted the analyses. While multiple strategies were implemented to mitigate this risk, some residual bias may persist. Second, a small number of participants in the UC group received certain intervention components. While this may have reduced the observed differences between groups, it is unlikely to compromise the validity of the findings. Third, the psychometric properties of the adapted social functioning and symptom assessment tools used by lay interviewers remain uncertain. Future studies should prioritise the validation of these instruments for use by non-specialist assessors to ensure measurement accuracy. Fourth, the need for multiple testing adjustments across primary outcome domains remains debatable. In our study, applying such adjustments could render the significance of socially meaningful activities non-significant. However, it could be argued that when a small set of pre-specified, related primary outcome domains is analysed, adjustments may not be necessary. Lastly, the study was conducted at a single-centre over a relatively short period, which may limit the generalisability of the findings to other settings and their long-term sustainability.

Future research should therefore examine the longer-term effects of the intervention beyond a 6-month period in a larger trial involving multiple settings and may extend into cost-effectiveness and implementation trials. Studies comparing the outcomes of this care approach with those of more intensive specialist-led interventions can also provide valuable insights into the relative costs and effectiveness of different service models.

In conclusion, the present study demonstrates the feasibility and effectiveness of a case management-based early intervention services involving lay health workers compared to usual care for individuals with early-phase psychosis. The programme can improve areas of social functioning over a relatively short period of time.

Contributors

TJ: conceptualisation, funding acquisition, investigation, methodology, supervision. SS: conceptualisation, methodology. TJ wrote the first draft of the manuscript and SS reviewed and provided input on the final draft. TJ had final responsibility for the decision to submit for publication. TJ and SS have full access to all the data in the study and accept responsibility to submit for the publication.

Data sharing statement

The de-identified data from this study may be made available to qualified researchers upon reasonable request, subject to compliance with ethical guidelines and data protection regulations. Researchers interested in accessing the data should submit a formal request to the corresponding author. Requests will be evaluated on a case-by-case basis. Access to the data will require a signed data use agreement. Currently, the data are not publicly available in an open-access repository due to the sensitive nature of the study population.

Use of generative AI in manuscript writing

ChatGPT was used to assist with language editing (grammar and spelling) in certain parts of the manuscript.

Declaration of interests

We declare no competing interests.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lansea.2025.100617.

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