Feasibility and Acceptability of a Telephone Support Intervention During Early Postnatal Period Among Teenage Mothers in Western Kenya: A Pilot Randomised Controlled Trial

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Abstract

Background: Teenage pregnancy, birth and the transition to motherhood present potentially stressful life events that may significantly affect maternal physical, social and mental wellbeing. For many young/teenage mothers, this transition may be a daunting task both in caring for themselves and their babies. Consequently, these mothers, and their babies, may experience considerable health risks, if unsupported. Innovative interventions such as telephone support have been considered promising in improving maternal and newborn care. The aim of this study was to pilot a postnatal telephone support intervention (TSI), informed through identification and prioritisation of the health needs and/or concerns of young/teenage mothers.

Methods: In this mixed-methods pilot trial, young/teenage mothers, in Kenya, were randomly assigned 1:1 to TSI or usual care/control groups and followed up for 10 weeks postpartum. Feasibility outcomes included recruitment, and attrition and retention rates. Outcome measures on maternal self-esteem (Rosenberg Self-esteem scale), postnatal depression (Edinburgh Postnatal Depression Scale), maternity social support (Maternity Social Support scale), postpartum bonding (Postpartum Bonding Instrument), and general maternal-infant health outcomes were assessed at 10 weeks postpartum. Interviews were used to assess feasibility and acceptability of TSI.

Results: Over three months, 91 young/teenage mothers were assessed for eligibility (recruitment rate=30/month), and 52 (57.1%) were randomised: 26 to TSI and 26 to usual care/control. Nine were lost to follow-up, with 43 (82.7%) retained for analysis. The overall attrition rate was high (17.3%) with differential attrition between groups (15.4% vs 19.2% for intervention and control groups respectively). Lack of personal mobile phones, network connectivity and insufficient electricity power were notable feasibility challenges. The impact of the TSI on maternal self-esteem and infant-focussed anxiety was promising, but a further adequately powered trial would be necessary to confirm this. The teenage mothers in the intervention group, however, valued the TSI.

Conclusions: The findings suggest that it is feasible to recruit young mothers for a similar definitive trial in the future. The study highlighted the potential areas in which TSI could provide meaningful, supportive in maternal and infant care. Overall, the findings are informative for a future definitive trial in low-and-middle-income settings.

Trial registration: Registered with Current Controlled Trials (ISRCTN15017499, 17/07/2017).

Background

Teenage pregnancy and motherhood remain a global issues of concern [1,2]. It was estimated that 21 million girls aged 15-19 years in developing regions became pregnant in 2016, of whom an estimated 12 million gave birth [1]. About half of teenage pregnancies (15-19 years) in developing regions are unintended [3], yet antenatal, intrapartum and postnatal services have not been adequately responsive to the needs of the adolescent population [1]. The World Health Organization report indicates that 49 out of

every 1000 births are among women aged 15–19 years, with higher rates being recorded in sub-Saharan Africa [4]. In Kenya, the national estimate of teenage pregnancy prevalence rate stands at 18% [5], with 378,397 adolescent girls aged 10-19 having presented with pregnancy to health facilities between July 2016 and June 2017 across all the 47 counties [6].

In low-income settings, 20% to 60% of young women's pregnancies and births are unintended [7], thereby putting many young women at a higher risk of pregnancy, labour, and childbirth complications [8-11]. Access to healthcare services, including skilled attendance before, during and after pregnancy is critical for positive outcomes for adolescents [12]. Limited or lack of continuity of care from service providers after birth often presents great challenges for new parents as they transit into parenthood [13]. Yet postnatal care remains one of the neglected areas in maternity care [4]. Supportive maternity care is therefore necessary for all women, including the young/teenage mothers who often are socially and economically disadvantaged [1]. The use of innovative approaches such as mobile health technologies may be a useful resource that can bridge this gap, leading to the optimisation of maternity services [14-21].

Methods

Design and objectives

The aim of this study was to test the feasibility and acceptability of a TSI by comparing telephone versus no support among teenage mothers during the early postnatal period in a low-and-middle income setting. The specific objectives of the study included: to assess the availability of good quality data in the study setting to support a larger study; to assess the acceptability of the TSI among teenage mothers and midwives; to observe the differences between the intervention and control group following the intervention; and to determine a primary outcome of interest and an appropriate research design for a definitive trial. This pilot RCT adopted the Kieser and Wassmer [22] estimate for a sample size of 20-40 for pilot studies, which is not based on powering to test for statistical significance. The study mimicked the design of a definitive RCT to inform the sample size determination for a definitive trial [23].

Setting

The study was conducted in two public tertiary teaching hospitals in Western region in Kenya, both of which serve a catchment population of over 15 million. In Kenya, the Demographic and Health Survey (KDHS) report [4] indicated that 18% of young women aged between 15 and 19 had already begun childbearing, 15% of whom were already mothers and an additional 3% were pregnant with their first child. The pregnancy rates increase rapidly with age, from 3% to 40% among those aged 15 and 19 years respectively [4].

Participants and procedure

Inclusion-exclusion criteria

Young/teenage mothers aged 12-19 years who gave birth to a singleton healthy baby at term, who owned a mobile phone and were able to use common mobile telephone operation services; and midwives and/or nurse-midwives with more than one year of experience working in maternity setting in the respective study centres were included in the study following consent. Mothers who were known to have a limited capacity to consent, such as those with recorded mental disability, were excluded.

Recruitment

Eligible mothers were recruited by a trained research assistant. Baseline data were collected once the participants had given informed consent or assent as applicable. A written assent was sought from the younger mothers (≤17 years) jointly with a parental consent, while those aged 18-19 years provided consent in an individual capacity as adults. Eligible midwives/nurse-midwives were also recruited at the end of the intervention by a research assistant upon consenting.

Randomisation, allocation and blinding

All eligible mothers who met the inclusion criteria were randomised into control or intervention groups. Group assignment was achieved using the SNOSE (sequentially numbered, opaque and sealed envelopes) approach [24], which was performed through a set of random allocation numbers generated by a computer, and carried out by someone independent of the intervention and data collection. Randomisation was stratified by age group (12-16 v 17-19 years) and was performed independently with no specific quota for the younger or older age group. To ensure blinding, research assistants (RAs) were recruited and trained at different times (recruitment, intervention and outcomes) to perform their respective roles in the study. The intervention midwife was blinded at the recruitment stage and was only provided with a list of the mothers randomly allocated to the intervention group by the the recruiting RA. At the end of the intervention, a second RA was recruited to collect outcome data from the two groups.

The intervention

Participants in the control group received the usual care as prescribed by the Ministry of Health guidelines (Kenya) [25], including postnatal counselling on self and infant care, family planning, infant immunisation and postnatal follow-up visits before discharge. Participants assigned to the intervention group received the usual care plus a TSI. The intervention was based on a mobile telephone support in form of motivational health messages developed through a Delphi technique [26]. The Delphi technique involved three rounds of iterative process in which midwives refined the content of the intervention with reflection upon their routine practices, thus providing clinical approach to the TSI. For example, regarding maternal health on breastfeeding and breast care, the text message was drafted to read: *'How are you today? Are you breastfeeding your baby well? Alternate breasts during feeding to prevent fullness. If your breasts are red, painful, swollen or cracked, pls report to the midwife or visit the hospital for assistance*' [week4]; while for the newborn/infant care domain, one of the texts read: *'Hello, Is the baby okay? Baby will be okay with breast milk alone and keep him warm always. Is the umbilicus red, with pus or has a*

bad smell? Is the baby having difficulty in breathing? If so, report immediately to the Nurse/hospital' [week1]. The messages were translated to Kiswahili language for ease of understanding.

The TSI was delivered in the form of weekly text messaging and a telephone call once every three weeks postpartum until the tenth week. The support intervention was provided by a trained RA regularly at scheduled dates for each of the participants. The participants were also given an option to call back as they wished for further informational support and/or clarification. The intervention midwife was asked to document such occasions (time/date of call and content domain of the information sought) in a field notebook.

Measures

Quantitative data were collected using validated tools. The *Maternity Social Support Scale (MSSS)* [27], Rosenberg's *Self-esteem Scale [28],* the *Edinburgh Postnatal Depression Scale (EPDS) [29]* and the *Postpartum Bonding Instrument* [30] were used to assess for maternal perceived social support, self-esteem, postnatal depression, and breastfeeding and mother-infant bonding respectively. An outcome-based questionnaire was used to assess for both maternal and infant health-related outcomes such as illness episodes/sepsis, contraception, self-medication [maternal], immunisation, breastfeeding, illness/sepsis, medication and weight gain [infant]. The questionnaires were piloted prior to the main study at a district hospital in the region. A structured questionnaire was used to collect baseline data. Secondary data (maternal health records) were also collected using a systematic data extraction form to ascertain the availability of quality data that may support a main trial. The questionnaires were translated into the Swahili language for participants whose language preference was Kiswahili and/or who did not understand English.

Qualitative data were collected using semi-structured interviews and focus group discussions (FGDs). The study initially set out to conduct FGDs concurrently after the questionnaire survey, and to account for group dynamics, separate focus groups had been planned for the two age groups. Nine individual interviews and three FGDs (5-6 participants each) and one FGD and six individual interviews were, however, conducted among the young mothers and the midwives respectively. The interviews mainly focussed on exploring participant views regarding their perceptions of the TSI. A short demographics questionnaire was used to record the midwives' biodata. The interview sessions were audio-recorded and were supplemented by concurrent taking of field notes.

Analysis

Quantitative data were double-entered into IBM SPSS Statistics (version 23) for analysis. To minimise researcher bias, the data were cross-checked for correct entry by someone other than the PI, who was blinded to group allocation. The PI was only unblinded to group allocation after analysis. The data were mainly analysed using appropriate descriptive statistics and the outcomes in the two arms of the study were compared descriptively. Recruitment rate, attrition rate and protocol adherence rate were estimated with 95% CIs, effect sizes for differences in frequencies (percentages) or means between groups. The

Pearson chi-square test was used to compare nominal variables, the Mann-Whitney U test to compare skewed numerical variables and independent-samples t-tests to compare non-skewed numerical variables. However, the test results were interpreted cautiously since the study was not powered to detect statistical significance. Qualitative data were analysed manually, using Framework analysis [31]. This approach enabled a priori and emergent issues to be explored. Five stages of analysis were completed, including familiarisation; development of a suitable framework; indexing of sections of transcripts through coding; organising the codes logically through charting; and mapping the data to reveal relationships, to discover an overall interpretation. This latter stage was conducted by the whole research team.

Results

Participant flow and attrition

The participant flow is reported according to the CONSORT statement [32]. Of the 91 eligible participants, fifty-two young mothers (57%) were enrolled in the study, out of whom 43 completed the follow-up and were analysed (attrition rate=17.3%). There was no protocol violation in the study. Recruitment, allocation, and sample attrition is shown in Figure 1.

Participant characteristics

There were no differences in characteristics at baseline between the two randomised groups (Table 1).

Table 1: Socio-demographic characteristics of the enrolled mothers by randomised group

		Intervention	Control	Total
		n(%)	n(%)	n(%)
Site	**MTRH**	11 (47.8)	11(52.4)	22 (51.2)
	KCGH	11 (52.2)	10(47.6)	21 (48.8)
Age group (years)	12-16	3 (13.6)	4(19.0)	7 (16.3)
	17-19	19 (86.4)	17(81.0)	36 (83.7)
Education level	Primary	10 (45.5)	7(33.3)	17 (39.5)
	Secondary	11 (50.0)	14(66.7)	25 (58.1)
	Tertiary	1 (4.5)	0(0.0)	1 (2.3)
Marital status	Married	4 (18.2)	8(38.1)	12 (27.9)
	Single	17 (77.3)	13(61.9)	30 (69.8)
	Separated	1 (4.5)	0(0.0)	1 (2.3)
Occupation	Self-employed	1 (4.5)	2(9.5)	3 (7.0)
	Unemployed	11 (50.0)	12(57.1)	23 (53.5)
	Student	10 (45.5)	7(33.3)	17 (39.5)
Religion	Catholic	4 (18.2)	3(14.3)	7 (16.3)
	Protestant	18 (81.8)	17(81.0)	35 (81.4)
	Muslim	0 (0.0)	1(4.8)	1 (2.3)
No. ANC visits	None	0 (0.0)	1 (4.8)	1 (2.3)
	One	2 (9.1)	4 (19.0)	6 (14.0)
	Two	2 (9.1)	0 (0.0)	2 (4.7)
	Three	5 (22.7)	2 (9.5)	7 (16.3)
	Four	11 (50.0)	9 (42.9)	20 (46.5)
	>Four	2 (9.1)	5 (23.8)	7 (16.3)
Primary support person	Parent	18 (81.8)	16 (76.2)	34 (79.1)
	Partner	3 (13.6)	4 (19.0)	7 (16.3)
	Friend	1 (4.5)	0 (0.0)	1(2.3)
	None	0 (0.0)	1 (4.8)	1(2.3)
Baby sex	Male	11(50.0)	9 (42.9)	20 (46.5)

	Female	11 (50.0)	12 (57.1)	23 (53.5)
Distance to clinic	<5km	11(50.0)	10 (47.6)	21(48.8)
	>5km	11 (50.0)	11 (52.4)	22 (51.2)

KEY: MTRH – Moi Teaching and Referral Hospital; KCGH – Kakamega County General Hospital

Feasibility outcomes

i) Quantitative

Over three months, 91 young/teenage mothers were assessed for eligibility (recruitment rate=30/month), 52 agreed to participate and 43 were retained (overall attrition rate=17.3%; differential attrition=15.4% vs 19.2% for intervention and control groups respectively). Only seven mothers were recruited and enrolled in the 12-16 age group across both study centres, with the youngest mother being aged fourteen. During recruitment, most mothers (79%) singled out their parents as their primary support persons after birth.

ii) Qualitative

During recruitment, it was observed that several mothers, who were otherwise eligible for recruitment, did not have personal mobile phones and so were consequently excluded. This finding was also noted during the midwives' interviews, who observed that many young/teenage mothers did not have mobile phones, as illustrated by the following excerpts:

'Many young adolescents mothers do not have phones, you may call when some are in school, some parents may not want them to receive the phone calls, and some may have sim cards, without cell phones……' [Midwife2, Site2]

'……some did not have telephones……and some were using the phone calls of their parents of whom when you would pass information, they would not faithfully transmit it to the recipients …..' [Midwife1, Site1]

Although the study initially set out to conduct FGDs concurrently after the questionnaire survey, this was not feasible as mothers came in at different times and thus it was not possible to constitute such FGDs. The FGDs were therefore planned and conducted on an agreed date and time with the mothers who were willing and consented to take part. Further, with the limited sample (n=7) recruited in the younger age group, individual interviews were only feasible for the younger mothers.

Acceptability/views on intervention

The intervention was acceptable by midwives and young mothers. Most midwives welcomed the idea of TSI and described it as 'a good idea or initiative' and thought that it would be acceptable among their fellow midwives and other healthcare providers. In addition, most midwives thought their institutions had the capacity to implement such innovative interventions as telephone support. As noted in the midwives'

FGD, one of the midwives observed that as midwives, they always wanted to know the progress of their clients/patients after discharge, as illustrated by the following excerpt:

"……as a midwife, I strongly concur with it [TSI] because many times, you hear my colleagues say, 'how is so and so, we took care of her, nursed her for three days and discharged her in a fairly stable condition'… this is prove that we are interested to know the progress of our patients" [Midwife1,FGD, Site1]

Interestingly, similar thoughts were also shared by another midwife at the second study centre, who stated:

'….. my personal experience as a midwife, I have really enjoyed on doing follow up, therefore, I know my fellow midwives will embrace and even other health workers, because, honestly after handling, treating, nursing and discharging a patient, you will keep on asking questions, wanting to know the patients' progress….' [Midwife3, Site2]

Similarly, young/teenage mothers perceived TSI as beneficial particularly in helping them to (effectively) transit and assume motherhood responsibilities. In particular, those who received the TSI highlighted perceived benefits, ranging from critical aspects such as breastfeeding support to infant care practices such as bathing and changing the baby, and including being reminded on their clinical appointments. The following excerpt clearly illustrates the mothers' views of the TSI:

'The telephone support and the text messages were of greater importance to me and my baby because I learnt many things…. it was my first time to give birth and my first experience on breastfeeding and I needed guidance….' [Young mother, 17 years, FGD_1Site1- participant in focus group discussion1 in Site1]

The midwives and young/teenage mothers also perceived telephone support to be cheaper than travelling to the clinic/hospital. Midwives felt that there are some aspects of care that could easily be addressed through telephone support, thereby helping mothers to save on fare as well as travel time to the clinic/hospital, as illustrated by the following excerpts:

'……and even it will be cheaper economically and less time consuming, as in, wasting time and fare travelling from the village to hospital to seek assistance….and yet it can be sorted out using a two minutes phone call or a mere text message' [Midwife1, Site1].

'I would really like the use of telephone support because some of us stay so far away from this hospital, so, it will be easier when we receive telephone support……' [Young mother, 19 years, FGD_2Site2 – participant in focus group discussion2 in study Site2]

Additionally, the potential benefits of TSI in maternal and infant care were elicited. Table 2 highlights the thematic areas of the qualitative findings regarding the perceptions of both midwives and young mothers of the intervention.

Table 2: Midwives' and young mothers' perceptions of telephone support intervention in maternal and infant care

Subthemes	Illustrative quotes
TSI as a means of knowledge dissemination to young mothers	*'It is [TSI] a good idea, because you will be passing forth knowledge, you know, you will be having one on one contact with them, so they will open up…….' [Midwife2, Site1]* *'Sending text messages and making phone calls as midwives to these young mothers will be very important, informing on cord care and some of the danger signs…….'[Midwife1, Site2]* *'Yes, I would have gained a lot because I would have been educated on breastfeeding and general guidance on baby care like especially on cord care' [Young mother, 19 years, FGD_3 Site 1]*
TSI as a means of bridging the gap in healthcare access	*'…..they need ….additional support through telephone support especially for those who can't travel to hospital……' [Midwife1, Site1]* *'……. it will help solving many issues, especially to the ignorant people in the society, hence will not be a must for a young adolescent mother to travel to hospital……' [Midwife2, Site 2]* *'Sending text messages and making phone calls as midwives to these young mothers will be very important …….in fact for those who are not educated in those remote villages need more health support than others……..' [Midwife1, Site2]*
TSI as a means of providing continuity of care/follow up	*'……as a midwife, I strongly concur with it because many times, you hear my colleagues say, "how is so and so, we took care of her, nursed her for three days and discharged her in a fairly stable condition" this is prove …. that we're interested to know the progress of our patients' [Midwife1, FGD,Site1]* *'Yes, if health workers send us the text messages, we will benefit because it's important for follow-up of our babies and our health too……' [Young mother, 17 years , FGD_3 Site1]*
Perceived effect/influence of TSI in MIC/midwifery	*'I strongly suggest that we also do the same to in antenatal period'* *[Midwife1, Site2]* *'……it [TSI] will greatly reduce both maternal and neonatal deaths because they will know how to handle the danger signs…..'[Midwife1, Site2]* *'In the recent past…… we have had neonatal and maternal deaths because of ignorance, so, if telephone support is implemented, it will help a great deal to curb these deaths...' [Midwife 8, FGD, Site1]*

Psychological outcomes

Although the study was not aimed at looking for statistical significance, the results offer some insight into the value of the tools used and may be incorporated in meta-analyses. There was no difference between groups in means for both postnatal depression (EPDS) (intervention group mean 8.5, control

group mean 8.6, p=0.916) and maternity social support (MSSS) (intervention group mean 22.9, control group mean 22.5, p=0.763), with small effect sizes (Cohen's d=-0.03 and 0.09 for EPDS and MSSS) respectively. Mothers in the intervention group appeared to have a very slightly higher self-esteem (mean=23.0, median=25) compared to the control group (mean=21.6, median=22); and appeared to have a slightly lower infant-focussed anxiety (mean=2.6, median=1.5) than the control group (mean=3.7, median=4.0). There was no statistically significant difference between groups in means for maternal self-esteem (SES), (p=0.087) and postpartum bonding factors (PBI-1, PBI-2 and PBI-3, all p>0.05), but there was a moderate effect size for SES (Cohen's d=0.54). Table 3 and Table 4 summarise these statistics.

Table 3: Descriptive statistics by randomised group

Outcomes	Intervention (n=22)			Control (n=21)		
	Mean (SD)	Median	95%CI	Mean (SD)	Median	95%CI
Postnatal depression index (EPDS)	8.5 (5.1)	8	6.2 to 10.8[]	8.6 (4.9)	9	6.4 to 10.9[]
Maternity social support (MSSS)	22.9 (4.5)	22	20.9 to 24.9 []	22.5 (3.8)	22	20.7 to 24.2 []
Maternal self-esteem (SES)	23.0 (4.5)	25	21 to 26 [][]	21.6 (3.2)	22	20.0 to 24.0 [][]
Postpartum bonding-Factor 1 (General)	6.8 (5.8)	6	4 to 8 [][]	6.7 (3.8)	7	4.0 to 10.0 [][]
Postpartum bonding-Factor 2 (Rejection & Pathological anger)	3.0 (3.4)	2	0.001 to 5 [][]	2.9 (2.8)	2	0.001 to 5.0 [][]
Postpartum bonding-Factor 3 (Infant-focussed anxiety)	2.6 (2.5)	1.5	1 to 5 [][]	3.7 (3.0)	4	0.001 to 6.0 [][]

[]95%CI for means; [][]95%CI for median

Table 4: Differences between randomised groups with effect sizes

Outcomes	Test statistic	p-value	95%CI for difference in means or medians	Effect size (Cohen's d)
Postnatal depression index (EPDS)	t=-1.07	0.916	-3.28 to 2.95 [1]	-0.03
Maternity social support (MSSS)	t=0.304	0.763	-2.19 to 2.97 [1]	0.09
Maternal self-esteem (SES)	MW Z=-1.709	0.087	0.001 to 4.00 [2]	0.54
Postpartum bonding-Factor 1 (General)	MW Z=-0.416	0.678	-3.00 to 1.00 [2]	0.13
Postpartum bonding-Factor 2 (Rejection & Pathological anger)	MW Z=-0.250	0.803	-2.00 to 2.00 [2]	0.07
Postpartum bonding-Factor 3 (Infant-focussed anxiety)	MW Z=-0.911	0.362	-3.00 to 1.00 [2]	0.28

[1]95%CI for difference in means; [2]95%CI for difference in median; MW=Mann Whitney test

Additionally, mothers who received telephone-support were less likely to report being ill (22.7% vs 71.4%; % difference=48.7%; 95 % CI for % difference=18.9% to 68.1%); experiencing difficulty in breastfeeding (9.1% vs 38.1%; %difference=29.0%; 95%CI for % difference=3.5% to 51.0%); and initiating early-weaning (22.7% vs 52.4%; % difference=29.7%; 95%CI for % difference=0.9% to 52.7%).

Discussion

The results of this pilot trial suggested that it is feasible to recruit young/teenage mothers for a definitive trial and that the TSI was acceptable to both midwives and mothers in the current setting. In this pilot study, recruitment was better in the older age group as only seven mothers were recruited in the 12-16 age group. Future trials in similar settings targeting similar a study population may have to devise alternative recruitment strategies, particularly for the younger mothers. The attrition was slightly but not significantly higher in the control group, suggesting that the more active engagement of the young mothers in the intervention group may have helped in retaining them. In terms of outcome comparison post-intervention, the remaining mothers may not have been completely comparable in terms of engagement. In view of a definitive trial, the high attrition rate and the differential group attrition would have to be considered, particularly in terms of whether and how the attrition rates could be reduced in a larger study.

It is worth noting that other circumstantial and practical issues may have also had an effect on recruitment and/or retention and overall enrolment in this study. A health workers' strike lasted almost the entire period of the study and data collection unfortunately coincided with the eve of political electioneering. For example, the health workers' strike may have influenced whether mothers would seek health services when there were no services rendered at the time, while electioneering may have had the

effect of some mothers translocating to their rural homes, thereby influencing recruitment, enrolment and/or retention rates.

Importantly, a definitive trial would need to devise ways of minimising attrition such as using a participant-tracking sheet to enhance retention of a reasonable sample size at the end of the trial. Attrition is a critical aspect in research especially in long term RCTs since it has direct implication on the statistical power, bias and generalisability of the findings, with attrition rates more than 20% posing serious threats to validity [33]. A definitive trial must recruit an adequate sample size that would permit external validity of the results [34-36]. Additionally, to address challenges such as lack of fare for hospital and/or study follow-up visits, definitive trials may consider following up participants within the primary level (peri-urban) facilities in the locality as an alternative option since these facilities are within a proximal reach to mothers seeking maternal and infant care services.

The significant influence of parental and family support on teenage mothers after birth needs consideration. Most young mothers stated their parents/guardian as primary source of support and continued relying on them for support or otherwise throughout the study period. This finding parallels the findings of a separate study in Kenya among pregnant and adolescent new mothers, which reported that maternal mother was the primary source of social support for pregnant and parenting teens [37]. Incidentally, a few of the mothers who were enrolled in the intervention group provided their parents' (mostly their mothers') telephone numbers to the intervention midwives for follow up. Most young mothers also had to seek the permission of their parents/guardians or ask the researcher to inform their parents about the appointment for data collection. Thus, striking a balance between ethical and practical issues such as autonomy and seeking consent was also paramount in this study population. Apart from the usual procedures in seeking informed consent and/or assent as necessary, it was evident that parental (or guardian) involvement was still necessary throughout the research process. This finding is an important consideration in the context of a feasibility study, particularly in similar settings. Thus, future trials in such settings may need to constantly involve teenage mothers' parents/guardians.

One of the inclusion criteria was ownership of a mobile phone, yet lack of phones was noted as a key challenge during recruitment and in the delivery of the entire package of the TSI. The TSI was received intermittently by some of the mothers in the intervention group. This was partly attributed to network connectivity issues, including lack of battery power or electricity at home (to charge their phones) when the TSI messages were transmitted. Similar trials in the future may therefore consider providing study-specific mobile phones to eligible participants to enhance recruitment rates and the provision of optimal TSI, thus objectively assessing the effect of TSI.

This study also generated important questions regarding tool development and validity that may be subject to future research. During data collection it was noted that one of the research instruments (*MSSS*) presented challenges to the mothers, some of whom could not respond to some of the questions despite adjustments after piloting the instruments. Reflectively, although the MSSS tool [27] was designed to assess maternal social support prenatally, its use in the postnatal context and among

young/teenage mothers who are more likely to be unmarried may therefore be debatable. Notably, four out of the six questions in the MSSS tool appeared to largely reflect mothers in some form of marital union, yet most of the mothers in the present study were single. The four items sought views ranging from the support they received from their husbands/partners to whether they experienced any form of conflict from their husbands/partners. Perhaps a similar tool that reflects the context (postnatal period), setting (low-and-middle-income) and the study population in question (teenage mothers) needs to be developed and validated. Importantly, the development of such a tool needs to be a specific study (tool development and validation), conducted independent of a trial or interventional study, and should incorporate the views and/or experiences of the population in question and other relevant stakeholders. Although other similar tools, such as the *multidimensional scale of perceived social support* [38], do exist, to our knowledge, there are no (similar) tools that have been developed and validated that adequately reflect the above triad.

Although pilot studies are not designed to estimate treatment effects since the limited sample sizes may often present unrealistic or biased estimates [34], it appeared the TSI had an effect of enhancing maternal self-esteem and reducing infant-related anxiety among the mothers. The intervention also appeared to positively influence both maternal and infant health outcomes such as breastfeeding, delayed weaning as well as reducing illness episodes. However, several studies have highlighted the potentially positive role of telephone support on breastfeeding outcomes [39-42]; stress and postnatal depression [21,43]; and overall maternal and infant wellbeing [19,21]. Importantly, systematic reviews on TSI [17,43,44] have highlighted the potential role of telephone support in improving maternal and infant care, but most of the trials which formed the evidence base of these reviews commonly involved adult mothers, and were mostly conducted in high-income countries. Thus, the effect of TSI among the young/teenage mothers in low-and-middle-income (LMIC) settings arguably remains vague. Therefore, in view of the feasibility findings highlighted in this pilot trial, a similar statistically powered definitive trial would enable better understanding of the effectiveness of TSI among this study population in LMIC settings. With limited RCTs on such interventions in LMICs, particularly in Africa, such definitive trials may contribute to the pool of evidence in systematic reviews of such interventions which is currently lacking or very limited.

Strengths and limitations

The strengths of this study include the development and piloting of an intervention which provided a practical clinical approach to the TSI because midwives refined the content of the intervention with reflection upon their routine practices. The use of SNOSE approach in randomisation and group assignment was appropriate and effective. Blinding was planned and achieved. Incidentally, the study also elicited the need for developing and validating a tool for assessing maternal social support that reflects the context of care and the study population (young/teenage mothers) in LMIC settings. That only seven mothers could be recruited in the younger age group is quite informative for a main trial as this implies that such trials may have to specifically target the older age group or find better approaches to engage with younger teenage mothers. Conducting the study in two centres also provided a better

means of assessing for feasibility as the findings, including qualitative data could be compared for consistency or otherwise.

The study, however, had some limitations. First, the overall attrition rate was relatively high and it was slightly higher in the control group. Second, during recruitment participants were provided with information sheets, and were given time to consider participating, before consenting. During this time period, and following randomisation, it is conceivable that participants from both trial arms may have shared information, thus affecting outcomes. Thus, future trials may consider adopting a cluster randomised design to minimise contamination.

Conclusions

The study findings suggest that it is feasible to recruit young mothers for a similar definitive trial in future, largely with the consideration of teenage mothers. The TSI was also acceptable to both midwives and young/teenage mothers. Larger definitive trials are warranted to provide precise estimates of the (potential) effect of TSI in thematic areas of maternity care. Overall, the findings are informative for a future definitive trial in LMIC settings such as Kenya.

Abbreviations

TSI: Telephone support intervention; FGD: Focus group discussion; LMIC: Low-and-middle-income; RA: Research assistant

Declarations

Ethical approval and consent to participate

Ethical approval was granted from Institutional Research Ethics Committees both at the University of Manchester (UMREC, reference: ethics/16427) and the Moi University/Moi Teaching & Referral Hospital Research Ethics Committee, reference: IREC/2016/209, FAN: IREC 1811. A written informed consent and assent, with a parental (or legal guardian) consent as applicable (minors), was obtained from the study participants. All ethical principles governing research were duly observed.

Consent for publication

Not applicable

Availability of data and materials

Data and materials are available on request from the corresponding author.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

EK conceived and designed the study, collected, analysed and interpreted the data, and wrote the first draft of the manuscript. MC, RS and TL made a contribution to the initial draft of the manuscript and provided critical revisions to the manuscript. All authors reviewed and approved the manuscript for submission.

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Figures

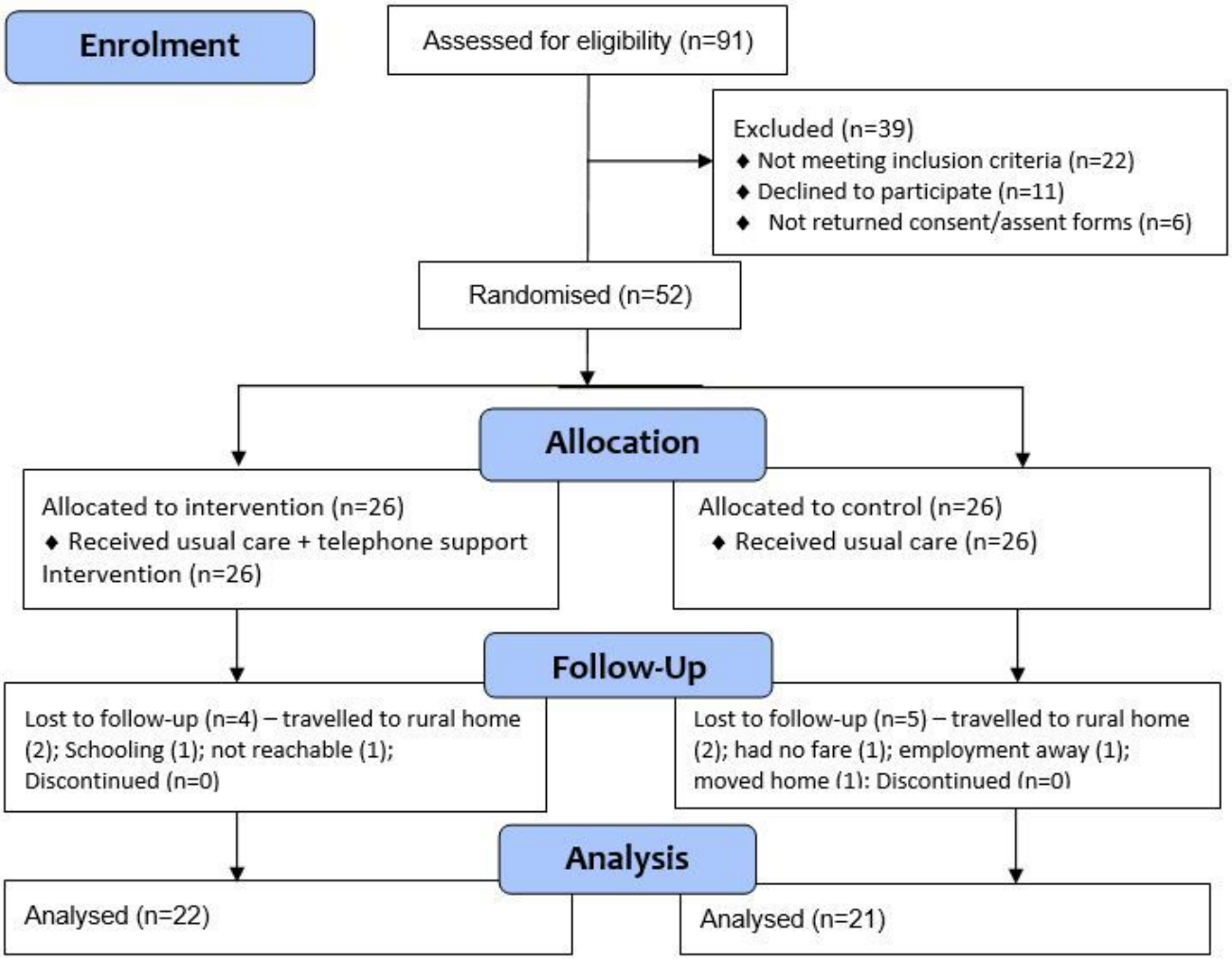

Figure 1

Participant flow chart