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TITLE: A supported psycho-educational intervention to improve family mental health following discharge from paediatric intensive care: feasibility and pilot randomised controlled trial

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ABSTRACT

Objective: To assess feasibility and pilot a supported psycho-educational tool to improve parent and child mental health following discharge from a paediatric intensive care unit (PICU), in preparation for a large randomised controlled trial (RCT).

Intervention: Families received a psycho-educational tool supported by a telephone call. The psycho-educational tool outlined the possible psychological reactions in children and parents alongside management advice, and the telephone call addressed each family's post-discharge experience, reinforced the psycho-educational material, and encouraged parents to put into practice the advice given.

Design: Feasibility assessment and pilot RCT of the intervention vs. treatment as usual (TAU) with an allocation of 2:1 in favour of the intervention.

Setting: A PICU in an acute care hospital in London, UK.

Participants: Parents of 31 children aged 4-16 years discharged from PICU: 22 allocated to the intervention and 9 to TAU.

Main Outcome Measures: The primary outcome was the number of feasibility criteria successfully met (linked to the intervention and the study design/procedures). Secondary outcomes were questionnaire data collected at 3-6 month follow-up assessing mental health function in parents and children.

Results: 3/6 intervention and 1/6 study design feasibility criteria were fully met. All unmet criteria could be addressed with minor or significant modifications to the protocol. The study was not powered to detect statistical differences, but to obtain initial estimates of effect of the intervention. At follow-up there was an overall trend for parents who received the intervention to report lower post-traumatic stress symptoms/risk in themselves and fewer behavioural and emotional symptoms in their children than TAU parents. There were also indications that the intervention may be selectively helpful for parents reporting high levels of stress during the PICU admission.

Conclusion: This feasibility and pilot RCT provided valuable information on the intervention and trial design for a full RCT.

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STRENGTHS AND LIMITATIONS

- There are few studies that have explored providing psychological support to families that have had a child admitted to PICU. This study provided important insights into the feasibility and acceptability of the novel intervention and study design/procedures before conducting a full RCT.
- The psycho-educational tool that formed part of the intervention was developed by expert and lay members including paediatricians, psychiatrists, psychologists, and families with lived experience of having a child admitted to PICU.
- The intervention studied is innovative in its approach, in that it does not require families to return to the hospital. Such a strategy may potentially serve to increase the uptake of support in this difficult to reach population.
- This feasibility pilot RCT was performed at a single centre.
- The sample size fell short of its target.

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INTRODUCTION

It is becoming increasingly evident that PICU admission can have far-reaching psychological after-effects including post-traumatic stress disorder (PTSD) in parents and children, parental anxiety and depression, and child emotional and behavioural problems(1-6). A recent review reported PTSD prevalence rates of 10%-21% in parents and 5%-28% in children following acute paediatric critical illness, with many other parents (up to 84%) suffering sub-clinical symptoms of PTSD, and with high correlations between parent and child PTSD symptoms(7).

There are established associations between both parental mental health problems and parenting changes following critical illness and child mental health symptoms(8). For example, some mothers become more protective and strict, whilst others make more allowances for their child's behaviour. Successful interventions aimed at improving parental mental health and parenting may therefore be expected to have a beneficial effect on both parent and child mental health.

There is currently no specific guidance in place for the psycho-social follow-up of families after paediatric critical illness, but there have been initiatives to evaluate different types of interventions. Melnyk et al.,(9) reported on the COPE programme, a 3-phase preventative educational-behavioural intervention programme of audiotapes, written information and an activity workbook for parents and children to complete during and after the admission. They found some beneficial psychological effects over one-year follow-up. However, this was a multi-faceted, comparatively complex and labour intensive intervention for young children (2-7 years old). The most significant beneficial findings were at the final one year follow-up, but they were subject to high attrition rates.

Other studies have involved less complex interventions, more in line with clinical practice, with offers of psycho-social parent follow-up to discuss any sequelae and provide support and guidance. These clinics have tended to be used by parents with mental health problems and the findings document small effect sizes in favour of the intervention for parental post-traumatic stress, anxiety, and depression. However, uptake rates have been disappointing, ranging from 25% to 37%(6, 10, 11).

We have developed an alternative intervention, offering psycho-education and guidance to parents following discharge from PICU by means of a carefully crafted psycho-educational intervention tool supported by a follow-up telephone call.

The primary objective of this study was to assess the feasibility of the supported psycho-educational intervention tool and the design and procedures of an evaluative study. It was intended that the assessment of the process outcomes would feed directly into planning a full trial, providing information that would ultimately improve its operational aspects(12, 13). As secondary objectives, we aimed to obtain initial estimates of the effect of the intervention on parent and child mental health, and explore the moderating effect of baseline parental stress. The study was not powered to assess statistical significance, and thus the analyses are mainly descriptive and should be interpreted with caution(14-16).

METHODS

Trial design

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This was a single-centre, parallel group, RCT. Parent-child pairs were individually randomised to either the intervention or treatment as usual (TAU) arm with an allocation ratio of 2:1 in favour of the intervention. Ethical permission for the study was obtained from the NHS Research Ethics Committee at London Riverside (#12/LO/1489), and the trial was registered with ClinicalTrials.gov (#NCT01737021).

Participants

Eligible participants were parents with a child aged 4-16 years old admitted to the PICU at St Mary's Hospital, London, UK, for at least 12 hours. Exclusion criteria included child death prior to discharge; discharge to palliative care; planned admissions; history of prior PICU admission; overseas address; or insufficient English to complete study questionnaires. Parents were approached by PICU consultants prior to their child's discharge from PICU and invited to participate. If parents provided permission, once their child had been discharged home, they were then sent detailed information sheets and consent forms with instructions to complete them. All parents gave informed consent before taking part. If the child was aged 8 years or older, they provided assent.

Intervention

The intervention had two phases: the first phase, (i.e., receipt of the psycho-educational tool), was planned to occur within 7 days of discharge from hospital and the second phase, (i.e., receipt of the telephone call), within 14 days of receiving the tool.

The psycho-educational tool consisted of a handbook developed by mental health and paediatric experts and parents with lived experience of having a child in PICU. The handbook covered three main areas: emotional recovery, behavioural recovery, and getting back to normal learning. The first section included a description of common emotional reactions in children, their siblings, and parents following discharge from PICU, with advice regarding their management. It also included an outline of when recovery becomes stalled by the development of PTSD, its manifestations, what treatments are available, and their rationale. The second section gave more detailed advice to parents about managing behavioural problems in children following hospital discharge. The third section addressed possible learning difficulties (e.g., slowed information processing, memory and attention problems) in the aftermath of the child's admission and provided guidance on how to support affected children. There was an additional section containing a list of contacts of possible sources of further support and advice.

The telephone call, conducted by the researcher, was used to discuss each family's post-PICU experience, reinforce the material in the handbook (thus ensuring all families were exposed to the information), and support families in putting into practice the advice given, if appropriate.

Outcomes

Primary outcome

There were 12 feasibility criteria used to judge the success of the trial (outlined in Table 1). Six criteria related to the intervention (covering timings, compliance, and evaluation) and six criteria related to the study design and procedures (covering screening, participation rate, acceptability of procedures, loss to follow-up, and the time-scale of data collection). The following classification system was outlined for both the intervention and study design according to the number of criteria met: 0-2/6: not feasible/acceptable;

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3-4/6: feasible/acceptable with modifications; 5/6: feasible/acceptable with close monitoring; 6/6: feasible/acceptable as it is.

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Table 1. Feasibility objectives

Feasibility objectives	Questions	A priori criterion for success	Outcome & contingency plans where appropriate
1. Feasibility/ acceptability of intervention	Can the handbook be delivered within 7 days of hospital discharge?	A median time of 6 days.	The median time was 17 days (IQR: 11, 31.25). ***>>Consent/deliver tool in PICU***
	Can the telephone call be delivered within 14 days of phase 1?	A median time of 14 days.	The median time was 21 days (IQR: 14, 24). ***>> Change target to 3-6 weeks.***
	Will parents read the handbook?	85% of parents will report reading the handbook.	All 17 (100%) responders said they had read the handbook.
	Will it be possible to engage parents in the full intervention?	95% of parents will receive the full intervention.	18/22 (82%) parents could be engaged in the full intervention. ***>> Rate reviewed as acceptable.***
	Will parents evaluate the intervention as useful?	80% of parents will evaluate the intervention as useful.	All 17 (100%) responders evaluated the intervention as useful.
	Will parents evaluate the intervention as appropriately timed?	80% of parents will deem timing of intervention as appropriate.	14/17 (82%) responders deemed the intervention as appropriately timed.
2. Feasibility/ acceptability of study design and procedures	How many families will be eligible to take part?	Mean of 5.3 eligible families are admitted to PICU per month.	The mean was 4 eligible families per month (range 1-8). ***>> Expand children's age range.***
	What is the participation rate?	75% of eligible families agree to participate in the study.	31/59 (53%) of families agreed to participate. ***>>Consent in PICU.***
	Are families willing to be randomised?	Less than 10% non-participation rate due to randomisation procedures.	31% of non-participation due to prospect of randomisation. ***>> Use patient and public involvement to improve explanation of research design.***
	Is the loss to follow-up rate reasonable?	Less than 20% of families will fail to complete outcome measures.	Overall loss to follow-up was 8/22 (26%). ***>> Reduce the number of assessment measures.***
	Can baseline data be collected in first week following discharge from hospital?	A median time from discharge to return of baseline questionnaires of 5 days.	The median time was 42 days (IQR: 35.5, 47.50). ***>> Baseline measures completed whilst on PICU.***
	Can families be followed-up within 3 to 6 months of PICU discharge?	The median time from PICU discharge to follow-up is 5 months or less.	The median time was 150 days (IQR: 122, 180).

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Secondary outcomes

Secondary outcomes included parent and child mental health after discharge from PICU, and exploration of the moderating effect of parental stress experienced during the PICU admission. Baseline and 3-6 month follow-up questionnaires were posted to families and returned using stamped addressed envelopes. We examined parental post-traumatic stress symptoms with the Impact of Events Scale (IES;17) and anxiety and depression with the Hospital Anxiety and Depression Scale (HADS;18). We assessed child emotional and behavioural difficulties with the parent-rated version of the Strength and Difficulties Questionnaire (SDQ;19) and sleep with the parent-rated Child Sleep Habits Questionnaire (CSHQ;20). For children aged 8-16 years, we assessed post-traumatic stress symptoms using the child-rated version of the Impact of Events Scale (IES-8;21).

Parent recollections of stress during their child's PICU admission were measured using the Parental Stressor Scale: Paediatric Intensive Care Unit (PSS: PICU;22). This questionnaire was completed retrospectively, once parents were back at home with their child.

Sample size

Consistent with pilot studies, no power analysis was conducted. We aimed to recruit a minimum of 12 participants in the TAU group based on suggested guidelines for pilot studies(23).

Randomisation

Participants were randomised to the intervention or to TAU using a computer-generated list of random numbers prepared by an independent statistician. Randomisation was stratified by age (4 to 10 years and 11 to 16 years of age) with a 1:1 allocation using random block sizes of 3 and 6, and with an allocation of 2:1 in favour of the intervention. The allocation sequence was concealed from the researcher enrolling and assessing participants and was stored with an administrator who had no other involvement in the trial. After the researcher obtained the parent and, if relevant, child's consent, they contacted the administrator for allocation consignment.

Blinding

Due to the nature of the trial, participants could not be blind to their allocation. There was one researcher recruiting, delivering the intervention, and assessing outcomes and thus it was not possible for them to be blind to intervention allocation.

Analytical methods

The primary outcome was the number of feasibility criteria successfully met. Feasibility outcomes were assessed using descriptive statistics and evaluated according to the success criteria outlined in Table 1. The number of criteria met was then assessed in line with the pre-specified classification system.

The secondary outcomes included parent and child mental health. The initial plan was to compare changes in mental health outcomes from baseline to follow-up across both groups. However, as it did not prove feasible to collect baseline data within the specified time frame, the analyses focused solely on the 3-6 month outcome data. Outcomes were analysed using both total symptom scores and risk of clinical disorder (i.e., "caseness"). We report descriptive data and effect sizes (Cohen's *d)* based on bootstrapped standard deviations of continuous data. Supplementary analyses involved a 2 (stress: high stress

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vs. low stress) x 2 (group: intervention vs. TAU) exploration of the role of parental stress on the efficacy of the intervention. Parents were classified as high or low stress according to a median split based on scores on the PSS: PICU.

RESULTS

Participant flow

Figure 1 outlines the number of parent-child pairs randomly assigned, those receiving the intended treatment, losses and exclusions after randomisation, and those analysed (with reference to secondary outcome follow-up data).

FIGURE 1 HERE

Recruitment

Eligible parent-child pairs were recruited from November 2012 to February 2014. Follow-up began in March 2013 and ended in July 2014. Families were approached for follow-up 3-6 months following their child's discharge from PICU: the median time from discharge to follow up was 150 days (range 101-245 days).

Numbers analysed

The mental health outcome data were assessed on an intention-to-treat basis and involved all parent-child pairs randomly assigned and providing follow-up data (17 in the intervention and 6 in TAU for parent reported data). Two parents in the intervention group were considered protocol violators as they did not receive the second phase of the intervention (i.e., the telephone call), but they remained in the analyses as they provided follow-up data.

Baseline Data

Characteristics of the parents and children that provided data in the two study groups are presented in Table 2 including age, gender, ethnicity, language, length of hospital stay, illness severity scores (PIM2;24), and parental stress scores.

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Table 2. Baseline demographic and clinic characteristics for families providing follow-up data in the intervention and treatment as usual groups

	n	Intervention group	n	Treatment as usual group
Parents				
Age, years	16	43.00 (42.00, 47.00)	6	36.00 (34.75,41.00)
Fathers	17	4 (24%)	6	1 (17%)
White UK	16	7 (44%)	5	2 (40%)
English primary language	17	14 (82%)	6	4 (67%)
PSS: PICU score	17	3.13 (2.43, 3.64)	6	3.12 (2.88, 3.26)
Children				
Age, years	17	6.00 (5.50, 10.50)	6	9.00 (5.50, 11.00)
Male	17	7 (41%)	6	3 (50%)
White UK	16	5 (31%)	6	3 (50%)
Length of stay in PICU, days	17	5.00 (4.00, 12.50)	6	6.00 (4.00, 9.50)
Length of stay in hospital, days	15	10.00 (6.00, 21.00)	5	7.00 (3.50, 17.00)
PIM2, %	17	4.10 (1.20, 7.68)	6	6.69 (4.33, 16.33)

Data are presented as median (inter-quartile range) or frequency (%).
PIM2 = Paediatric Index of Mortality 2
PSS:PICU = Parental Stressor Scale: Paediatric Intensive Care Unit

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Outcomes and estimations

Primary outcomes

Met and unmet outcomes together with suggested modifications/protocol amendments are outlined in Table 1.

Three out of six *intervention* feasibility and acceptability criteria were fully met: all parents said they had read the handbook, all evaluated it as useful, and most (82%) deemed it appropriately timed. Criteria not met included the time it took to execute both phases of the intervention, as well as the percentage of parents that engaged in the full intervention. Overall, the intervention was deemed feasible/acceptable with modifications.

In terms of the feasibility and acceptability of the *study design and procedures*, one criterion was fully met, namely families could be followed-up a median of five months post PICU discharge. Criteria not met included the number of eligible families admitted to PICU per month, the participation rate, the refusal rate (due to randomisation), the number lost to follow-up, and the time taken to return the baseline questionnaires. Thus, the study design and procedures were not deemed feasible/acceptable.

Additional comments collated from parents in the intervention group indicated that the information in the handbook made them feel more prepared for life after PICU (82%) and less anxious or concerned (77%). Almost half of the parents (47%) had shared the handbook with others including partners, relatives, their children (including the child admitted to PICU and their siblings), and teachers. With regards to the telephone call, 94% judged the timing to be good, 82% reported finding it useful, and 59% thought that a single call was sufficient (35% were unsure about this).

Secondary outcomes

Parent and child mental health outcomes are outlined in Table 3. Intervention parents reported fewer post-traumatic stress symptoms and risks (small effect sizes), but there was little difference in anxiety and depression scores. Because of questionnaire age-range criteria and missing data the child outcomes are based on reduced total numbers (particularly so for the IES-8). Table 3 shows that the children whose parents received the intervention had lower levels of total behavioural and emotional difficulties (moderate effect sizes), but there were negligible differences in sleep symptoms. On the IES-8, children in the intervention reported more post-traumatic stress symptoms and risks (moderate effect sizes).

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Table 3. Mental health outcomes at 5 months post PICU discharge for families providing follow-up data in the intervention and treatment as usual groups

	n	Intervention group	n	Treatment as usual group	Effect size *d*
Parent outcomes					
Impact of Events Scale:					
Post-traumatic symptoms total score	17	19.47 (11.64, 26.62)	6	25.83 (11.47, 39.00)	0.38
Caseness (%)	17	3 (18%)	6	2 (33%)	0.34
Hospital Anxiety and Depression Scale:					
Anxiety total score	17	6.47 (4.53, 8.54)	6	7.17 (4.20, 11.00)	0.17
Caseness (%)	17	6 (35%)	6	2 (33%)	0.04
Depression total score	17	2.76 (1.33, 4.45)	6	3.00 (0.00, 5.96)	0.07
Caseness (%)	17	2 (12%)	6	1 (17%)	0.13
Child outcomes					
Strength and Difficulties Questionnaire:					
Total Difficulties total score	14	9.21 (6.93, 11.31)	6	11.83 (6.50, 16.06)	0.59
Caseness (%)	14	0 (0%)	6	1 (17%)	0.75
Child Sleep Habits Questionnaire:					
Sleep disturbance total score	13	47.08 (42.72, 52.15)	6	48.00 (42.85, 52.83)	0.13
Caseness (%)	13	11 (85%)	6	5 (83%)	0.03
Impact of Events Scale-8:					
Post-traumatic symptoms total score	3	13.00 (1.00, 20.00)	3	8.33 (0.00, 22.00)	0.57
Caseness (%)	3	2 (67%)	3	1 (33%)	0.71

Data are presented as means (BCa 95% CI) or frequency (%).

Effect sizes for continuous data are based on boostrapped SD. An effect size between 0.2 and 0.5 being considered a small effect, 0.5 and 0.8 a moderate effect, and 0.8 and above a large effect.

Scores of 35 or more for parents on the Impact of Events Scale indicate high risk for PTSD; scores of 8 or more on either sub-scale of the Hospital Anxiety and Depression Scale indicate high risk for clinical disorder.

Scores of 17 or more on the parent-rated Strength and Difficulties Questionnaire indicate high risk for mental health disorder; scores of 41 or more on the parent-rated Child Sleep Habits Questionnaire indicate high risk for sleep disorder; scores of 17 or more on the child-rated version of the Impact of Events Scale-8 indicate high risk for PTSD.

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Exploration of the moderating effect of parental stress on the effect of the intervention was conducted for parent outcomes. Parents were classified as “high stress” or “low stress” using the total PSS: PICU median cut-off of 3.12.

The symptom scores split by admission stress levels and treatment group are outlined graphically in Figure 2. “High stress” parents in the intervention group reported fewer post-traumatic stress (*d*=1.06), anxiety (*d*=0.62), and to a lesser extent depression symptoms (*d*=0.19) than “high stress” TAU parents. However, “Low stress” parents in the intervention group reported more post-traumatic stress (*d*=0.47) and anxiety (*d*=0.35*)* though fewer depressive symptoms (*d*=0.34) in comparison to “low stress” TAU parents. Examination of data by percentages at risk for mental health disorders revealed a similar pattern of results.

FIGURE 2 HERE

DISCUSSION

We report the results of a combined feasibility and pilot RCT of a novel supported psycho-educational intervention to help parents of children admitted to PICU recognise and manage possible psychological sequelae in themselves and their children. The results confirm the acceptability and feasibility of many aspects of the intervention, with clear indications of modifications that could be made to improve on this further. Although the study design and procedures were not deemed feasible, the data we gathered provided sufficient information to guide significant protocol amendments in order to ensure the overall feasibility of a future full efficacy trial. The comparison of mental health outcomes in the intervention and TAU groups 3-6 months following PICU discharge show the intervention to hold promise for reducing post-traumatic stress in parents and emotional and behavioural problems in children, with the parental effects being especially prominent for those with high levels of stress during the PICU admission.

Feasibility findings

Out of the twelve feasibility criteria developed *a priori* for the study, three out of six relating to the intervention and one out of six addressing the study design and procedures were fully met. All unmet criteria were reviewed and appropriate modifications to the intervention were formulated as well as more significant amendments to the study design and procedures, leading us to conclude that the revised protocol would be acceptable and feasible for a larger study. Changes include 1) obtaining consent, collecting baseline data, randomising, and delivering the psycho-educational tool whilst the child and their family are still on PICU (to help increase the participation rate, ensure baseline data is collected in a timely manner, and that the psycho-educational tool is delivered promptly); 2) a delay of the supportive telephone call to 3-6 weeks after PICU discharge (in line with a time-frame that was logistically viable and also considered acceptable by parents); 3) expanding the age range of children admitted into the study (to increase the number of eligible families); 4) reducing the number of assessment measures (to lessen the burden on participants and decrease the likelihood of attrition); and 5) providing a better explanation of the rationale for randomisation (to reduce non-participation on these grounds).

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Notably, once parents were recruited to the study, it proved possible to provide the full intervention to 82%. This was initially considered an unmet criterion, as the target was 95%. Upon reflection, 82% was deemed acceptable, as this is a considerably higher rate than in previous studies offering outpatient consultations to families, where uptake in the intervention group ranged from 25% to 37% (6, 10). This suggests that providing after care via a supported psycho-educational tool may be an effective way of increasing uptake of support in this difficult to reach population.

Secondary outcomes

Our study was not powered to identify statistically significant differences between the intervention and TAU groups, but our results are suggestive of clinically meaningful differences and potential benefit from the supported psycho-educational intervention for parent and child mental health. Five months after PICU discharge a third of parents in the control group were identified as at risk for PTSD and general anxiety disorders, which is compatible with results from previous short-term outcome studies of critical illness(6, 10, 25, 26). However, the intervention parents had fewer post-traumatic stress symptoms and less risk for PTSD. Although they also had fewer anxiety or depressive symptoms, effect sizes were smaller, suggesting an advantage of the intervention for PTSD risk. Similarly, the comparatively high rates of child emotional and behavioural difficulty in the TAU group were in line with those in previous studies of children following critical illness(1, 25), and the intervention group had fewer emotional and behavioural symptoms and risk for mental health problems, although the opposite was the case for PTSD symptoms in the particularly small number of children completing questionnaires. The findings, thus, tentatively suggest that families receiving the intervention may be better adjusted mentally at follow-up.

Our results further indicate that the effects of the intervention on parents may have been modulated by baseline parental stress. Parents who reported having been particularly highly stressed during the PICU admission scored considerably worse than other parents on PTSD and anxiety, but they also seemed to benefit from the intervention. Conversely, and albeit with smaller effect sizes, parents categorised as “low stress” in the intervention group had higher PTSD and anxiety scores than those in the TAU group at follow-up. This would seem to indicate that the intervention may only be beneficial for parents who are highly stressed whilst in PICU, and that it may increase symptom reporting by low stressed parents, in the same way that emotional “debriefing” after other stressful events may have adverse mental health effects in some people(27). Nevertheless, our intervention is considerably less emotionally involving than debriefing. Psycho-educational interventions such as ours may not necessarily have adverse effects(27) making this issue one requiring further elucidation.

Strengths and limitations

Strengths of this study include its basis on empirical studies of PICU mental health outcomes, drawing and benefiting from the experience of previous well thought out, but ultimately unsuccessful intervention studies; the joint expert and lay approach to the development of the psycho-educational materials; the likely cost-effectiveness of the intervention; the careful approach to assessing feasibility and acceptability of both the intervention and study design/procedures. Limitations include falling short of the suggested minimum sample size for pilot studies; recruiting from a single centre, making

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generalisability uncertain; and the retrospective assessments of parental stress experienced whilst on PICU. As intended, however, the study opens the way for a future full RCT of the intervention.

Conclusion

Our study indicates that our novel intervention, a psycho-educational tool supported by a directed telephone call, is acceptable to parents. Although aspects of the intervention and study design/procedures were not deemed feasible, we were able to address each unmet criteria, putting protocol modification/amendments in place. In addition, preliminary results indicate the potential beneficial effects of this supported psycho-educational tool for the mental health of parents and children, especially in parents with higher stress levels during the PICU admission. However, this, together with any possible adverse effects on low stressed parents, needs to be subjected to a fully powered study before this intervention can be widely introduced into clinical practice.

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Competing interests

None declared.

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Contributors

All authors included on this paper fulfil the ICMJE criteria for authorship. All authors were involved in the study conception and design. LCA, SN, and MEG obtained the funding. LCA, SN, and MC recruited participants or collected and collated data. LCA analysed the data. All authors were involved in the interpretation of data. LCA and MEG drafted the article and SN, MC, and BV revised it critically for important intellectual content. All authors approved the final version of the work and agree to be accountable for all aspects of the work.

Ethical approval

The NHS Research Ethics Committee at London Riverside approved the study.

Data sharing

No additional data are available.

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FIGURE LEGENDS

Figure 1. Participant flow chart

Figure 2. Mental health symptoms (total scores) in parents at 5 months post PICU discharge in the intervention (Rx) and treatment as usual (TAU) groups, split according to PSS: PICU stress score (H=high stress; L=low stress)

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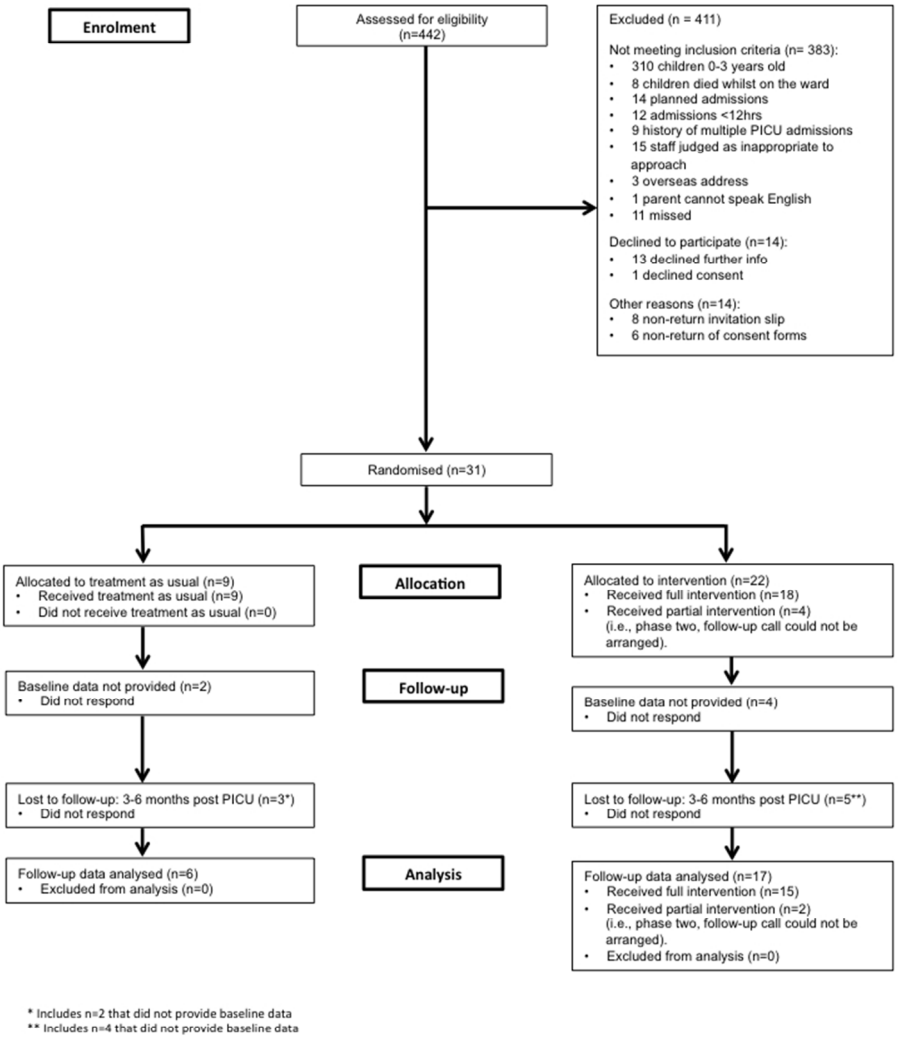

Figure 1. Participant flow chart
254x338mm (72 x 72 DPI)

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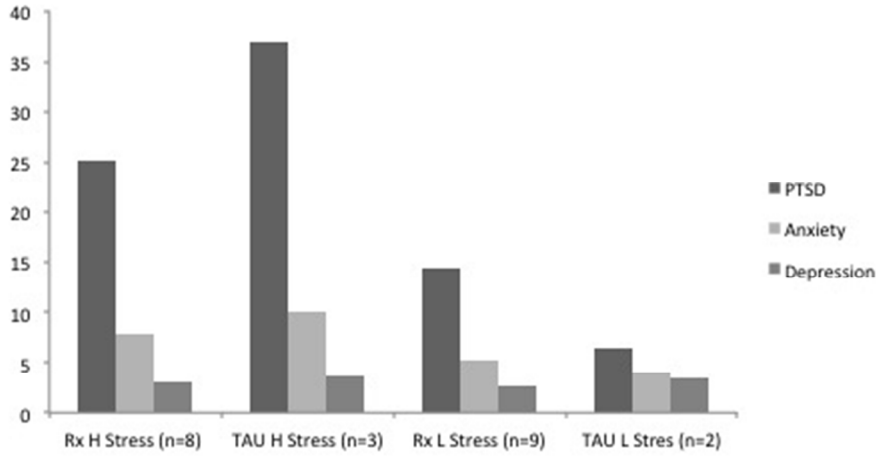

Figure 2. Mental health symptoms (total scores) in parents at 5 months post PICU discharge in the intervention (Rx) and treatment as usual (TAU) groups split according to PSS: PICU stress score (H=high stress; L=low stress)
162x84mm (72 x 72 DPI)

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TITLE: A supported psycho-educational intervention to improve family mental health following discharge from paediatric intensive care: feasibility and pilot randomised controlled trial

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Feasibility studies; Intervention studies; Follow-up studies; Post-traumatic stress; intensive care

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ABSTRACT

Objective: To assess feasibility and pilot a supported psycho-educational tool to improve parent and child mental health following discharge from a paediatric intensive care unit (PICU), in preparation for a large randomised controlled trial (RCT).

Design: Feasibility assessment and single-centre, parallel group, pilot RCT. A concealed computer generated list was used to randomise participants, with an allocation of 2:1 in favour of the intervention.

Setting: A PICU in an acute care hospital in London, UK.

Participants: 31 parents of children aged 4-16 years old admitted to PICU.

Intervention: Parents received a psycho-educational tool supported by a telephone call. The psycho-educational tool outlined the possible psychological reactions in children and parents alongside management advice. The telephone call addressed each family's post-discharge experience, reinforced the psycho-educational material, and encouraged parents to put into practice the advice given.

Main Outcome Measures: The primary outcome was the number of feasibility criteria successfully met (linked to the intervention and the study design). Secondary outcomes were questionnaire data collected at 3-6 month follow-up assessing mental health in parents and children.

Results: 31 parents were randomised (intervention n=22; TAU n=9). 23 parents were included in the analysis of secondary outcomes (intervention n=17; TAU n=6). 3 (of 6) intervention and 1 (of 6) study design feasibility criteria were fully met. All unmet criteria could be addressed with minor or significant modifications to the protocol. At follow-up there was a tendency for parents who received the intervention to report lower post-traumatic stress symptoms in themselves and fewer emotional and behavioural difficulties in their children than TAU parents. This needs to be explored in a fully powered trial.

Conclusion: This feasibility and pilot RCT provided valuable information on the intervention and trial design for a full RCT.

Trials Registration: ClinicalTrials.gov; NCT01737021.

Funding: Children of St Mary's Intensive Care (COSMIC).

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STRENGTHS AND LIMITATIONS

- There are few studies that have explored providing psychological support to families that have had a child admitted to PICU. This study provided important insights into the feasibility and acceptability of the novel intervention and study design/procedures before conducting a full RCT.
- The psycho-educational tool that formed part of the intervention was developed by expert and lay members including paediatricians, psychiatrists, psychologists, and families with lived experience of having a child admitted to PICU.
- The intervention studied is innovative in its approach, in that it does not require families to return to the hospital. Such a strategy may potentially serve to increase the uptake of support in this difficult to reach population.
- This feasibility pilot RCT was performed at a single centre.
- The sample size fell short of its target.

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INTRODUCTION

It is becoming increasingly evident that PICU admission can have far-reaching psychological after-effects including post-traumatic stress disorder (PTSD) in parents and children, parental anxiety and depression, and child emotional and behavioural problems(1-6). A recent review reported PTSD prevalence rates of 10%-21% in parents and 5%-28% in children following acute paediatric critical illness, with many other parents (up to 84%) suffering sub-clinical symptoms of PTSD, and with high correlations between parent and child PTSD symptoms(7).

There are established associations between both parental mental health problems and parenting changes following critical illness and child mental health symptoms(8). For example, some mothers become more protective and strict, whilst others make more allowances for their child's behaviour. Successful interventions aimed at improving parental mental health and parenting may therefore be expected to have a beneficial effect on both parent and child mental health.

In 2009, NICE issued guidance on rehabilitation in adults after critical illness, recommending psychological follow-up for survivors and their family(9). However, there is currently no formal guidance in place for the follow up of parents and their children after paediatric critical illness. There have been initiatives to evaluate different types of interventions. Melnyk et al.,(10) reported on the COPE programme, a 3-phase preventative educational-behavioural intervention programme of audiotapes, written information and an activity workbook for parents and children to complete during and after the admission. They found some beneficial psychological effects over one-year follow-up. However, this was a multi-faceted, comparatively complex and labour intensive intervention for young children (2-7 years old). The most significant beneficial findings were at the final one year follow-up, but they were subject to high attrition rates.

Other studies have involved less complex interventions, more in line with clinical practice, with offers of psycho-social parent follow-up to discuss any sequelae and provide support and guidance. These clinics have tended to be used by parents with mental health problems and the findings document small effect sizes in favour of the intervention for parental post-traumatic stress, anxiety, and depression. However, uptake rates have been disappointing, ranging from 25% to 37%(6, 11, 12).

We have developed an alternative intervention, offering psycho-education and guidance to parents following their child's discharge from PICU by means of a carefully crafted written psycho-educational intervention tool supported by a follow-up telephone call. This aimed to increase accessibility of the intervention. Information based interventions have been evaluated positively by parents and shown to be effective in reducing the parental stress associated with transfer from PICU to the general paediatric ward(13, 14). There are promising results in the use of such interventions following paediatric injury(15, 16). However, the impact of post-discharge psycho-education on psychological sequelae in parents and their children following PICU admission has not been formally assessed. Screen and intervene approaches that include parental guidance on how to manage PTSD symptoms in children and psychosocial support for families have been recommended after childhood traumatic events (17*)*. We therefore complemented the self-help psycho-educational tool with a supportive guidance telephone session.

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The primary objective of this study was to assess the feasibility of the supported psycho-educational intervention tool and the design and procedures of an evaluative study. It was intended that the assessment of the process outcomes would feed directly into planning a full trial, providing information that would ultimately improve its operational aspects(18, 19). As secondary objectives, we aimed to obtain initial estimates of the effect of the intervention on parent and child mental health, and explore the moderating effect of baseline parental stress(11, 20). The study was not powered to assess statistical significance, and thus the analyses are mainly descriptive and should be interpreted with caution(21-23).

METHODS

Trial design

This was a single-centre, parallel group, RCT. Parents were individually randomised to either the intervention or treatment as usual (TAU) arm with an allocation ratio of 2:1 in favour of the intervention. Ethical permission for the study was obtained from the NHS Research Ethics Committee at London Riverside (#12/LO/1489), and the trial was registered with ClinicalTrials.gov (#NCT01737021).

Participants

Eligible participants were parents with a child aged 4-16 years old admitted to the PICU at St Mary's Hospital, London, UK, for at least 12 hours. Exclusion criteria included child death prior to discharge; discharge to palliative care; planned admissions; history of prior PICU admission; overseas address; or insufficient English to complete study questionnaires. Parents were approached by PICU consultants prior to their child's discharge from PICU and invited to participate. If parents provided permission, once their child had been discharged home, they were then sent detailed information sheets and consent forms with instructions to complete them. All parents gave informed consent before taking part. If the child was aged 8 years or older, they provided assent to complete a self-report questionnaire at follow-up.

Intervention

The intervention had two phases: the first phase, (i.e., receipt of the psycho-educational tool), was planned to occur within 7 days of discharge from hospital and the second phase, (i.e., receipt of the telephone call), within 14 days of receiving the tool.

The psycho-educational tool consisted of a handbook developed by mental health and paediatric experts and parents with lived experience of having a child in PICU. The handbook covered three main areas: emotional recovery, behavioural recovery, and getting back to normal learning. The first section included a description of common emotional reactions in children, their siblings, and parents following discharge from PICU, with advice regarding their management. It also included an outline of when recovery becomes stalled by the development of PTSD, its manifestations, what treatments are available, and their rationale. The second section gave more detailed advice to parents about managing behavioural problems in children following hospital discharge. The third section addressed possible learning difficulties (e.g., slowed information processing, memory and attention problems) in the aftermath of the child's admission and provided guidance on how to support affected children. There was an additional section containing a list of contacts of possible sources of further support and advice.

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The telephone call, conducted by the researcher, was used to discuss each family's post-PICU experience, reinforce the material in the handbook (thus ensuring all families were exposed to the information), and support families in putting into practice the advice given, if appropriate.

Outcomes

Primary outcome

There were 12 feasibility criteria used to judge the success of the trial (outlined in Table 1). Six criteria related to the intervention (covering timings, compliance, and evaluation) and six criteria related to the study design and procedures (covering screening, participation rate, acceptability of procedures, loss to follow-up, and the time-scale of data collection). The following classification system was outlined for both the intervention and study design according to the number of criteria met: 0-2/6: not feasible/acceptable; 3-4/6: feasible/acceptable with modifications; 5/6: feasible/acceptable with close monitoring; 6/6: feasible/acceptable as it is.

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Table 1. Feasibility objectives

Feasibility objectives	Questions	A priori criterion for success	Criterion met?	Outcome & contingency plans where appropriate
1. Feasibility/ acceptability of intervention	Can the handbook be delivered within 7 days of hospital discharge?	A median time of 6 days.	×	The median time was 17 days (IQR: 11, 31.25). ***>>Consent/deliver tool in PICU***
	Can the telephone call be delivered within 14 days of phase 1?	A median time of 14 days.	×	The median time was 21 days (IQR: 14, 24). ***>> Change target to 3-6 weeks.***
	Will parents read the handbook?	85% of parents will report reading the handbook.	✓	All 17 (100%) responders said they had read the handbook.
	Will it be possible to engage parents in the full intervention?	95% of parents will receive the full intervention.	(✓)	18/22 (82%) parents could be engaged in the full intervention. ***>> Rate reviewed as acceptable.***
	Will parents evaluate the intervention as useful?	80% of parents will evaluate the intervention as useful.	✓	All 17 (100%) responders evaluated the intervention as useful.
	Will parents evaluate the intervention as appropriately timed?	80% of parents will deem timing of intervention as appropriate.	✓	14/17 (82%) responders deemed the intervention as appropriately timed.
2. Feasibility/ acceptability of study design and procedures	How many families will be eligible to take part?	Mean of 5.3 eligible families are admitted to PICU per month.	×	The mean was 4 eligible families per month (range 1-8). ***>> Expand children's age range.***
	What is the participation rate?	75% of eligible families agree to participate in the study.	×	31/59 (53%) of families agreed to participate. ***>>Consent in PICU.***
	Are families willing to be randomised?	Less than 10% non-participation rate due to randomisation procedures.	×	31% of non-participation due to prospect of randomisation. ***>> Use patient and public involvement to improve explanation of research design.***
	Is the loss to follow-up rate reasonable?	Less than 20% of families will fail to complete outcome measures.	×	Overall loss to follow-up was 8/22 (26%). ***>> Reduce the number of assessment measures.***
	Can baseline data be collected in first week following discharge from hospital?	A median time from discharge to return of baseline questionnaires of 5 days.	×	The median time was 42 days (IQR: 35.5, 47.50). ***>> Baseline measures completed whilst on PICU.***
	Can families be followed-up within 3 to 6 months of PICU discharge?	The median time from PICU discharge to follow-up is 5 months/150 days or less.	✓	The median time was 150 days (IQR: 122, 180).

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Secondary outcomes

Secondary outcomes included parent and child mental health after discharge from PICU, and exploration of the moderating effect of parental stress experienced during the PICU admission. Baseline and 3-6 month follow-up questionnaires were posted to families and returned using stamped addressed envelopes. We examined parental post-traumatic stress symptoms with the Impact of Events Scale (IES;24) and anxiety and depression with the Hospital Anxiety and Depression Scale (HADS;25). We assessed child emotional and behavioural difficulties with the parent-rated version of the Strength and Difficulties Questionnaire (SDQ;26) and sleep with the parent-rated Child Sleep Habits Questionnaire (CSHQ;27). For children aged 8-16 years, we assessed post-traumatic stress symptoms using the child-rated version of the Impact of Events Scale (IES-8;28).

Parent recollections of stress during their child's PICU admission were measured using the Parental Stressor Scale: Paediatric Intensive Care Unit (PSS: PICU;29). This questionnaire was completed retrospectively, once parents were back at home with their child.

Sample size

Consistent with pilot studies, no power analysis was conducted. We aimed to recruit a minimum of 12 participants in the TAU group based on suggested guidelines for pilot studies(30).

Randomisation

Participants were randomised to the intervention or to TAU using a computer-generated list of random numbers prepared by an independent statistician. Randomisation was stratified by age (4 to 10 years and 11 to 16 years of age), with an allocation of 2:1 in favour of the intervention using random block sizes of 3 and 6. The allocation sequence was concealed from the researcher enrolling and assessing participants and was stored with an administrator who had no other involvement in the trial. After the researcher obtained the parent's consent and, if relevant, child's assent, they contacted the administrator for allocation consignment.

Blinding

Due to the nature of the trial, participants could not be blind to their allocation. There was one researcher recruiting, delivering the intervention, and assessing outcomes and thus it was not possible for them to be blind to intervention allocation.

Analytical methods

The primary outcome was the number of feasibility criteria successfully met. Feasibility outcomes were assessed using descriptive statistics and evaluated according to the success criteria outlined in Table 1. The number of criteria met was then assessed in line with the pre-specified classification system.

The secondary outcomes included parent and child mental health. The initial plan was to assess changes in mental health outcomes from baseline to follow-up across both groups. However, as it did not prove feasible to collect baseline data within the specified time frame, we focused solely on the 3-6 month outcome data. Outcomes were assessed using total symptom scores. Descriptive data and effect sizes (Cohen's *d)* based on bootstrapped standard deviations of continuous data are reported. We intended to conduct supplementary analyses involving a 2 (stress: high stress vs. low stress) x 2

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(group: intervention vs. TAU) exploration of the role of parental stress on the efficacy of the intervention. However, this was precluded due to the small sample size.

RESULTS

Participant flow

Figure 1 outlines the number of parent-child pairs randomly assigned, those receiving the intended treatment, losses and exclusions after randomisation, and those analysed (with reference to secondary outcome follow-up data).

FIGURE 1 HERE

Recruitment

Eligible parent-child pairs were recruited from November 2012 to February 2014. Follow-up began in March 2013 and ended in July 2014. Families were approached for follow-up 3-6 months following their child's discharge from PICU: the median time from discharge to follow up was 5 months (150 days; range 101-245 days).

Numbers analysed

The mental health outcome data were assessed on an intention-to-treat basis and involved all parent-child pairs randomly assigned and providing follow-up data (17 in the intervention and 6 in TAU for parent reported data). Two parents in the intervention group were considered protocol violators as they did not receive the second phase of the intervention (i.e., the telephone call), but they remained in the analyses as they provided follow-up data.

Baseline Data

Characteristics of the parents that provided data and their children, split by trial arm, are presented in Table 2 and include age, gender, ethnicity, language, length of hospital stay, illness severity scores (PIM2;31), and parental stress scores.

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Table 2. Baseline demographic and clinic characteristics for families providing follow-up data in the intervention and treatment as usual groups

	n	Intervention group	n	Treatment as usual group
Parents				
Age, years	16	43.00 (42.00, 47.00)	6	36.00 (34.75,41.00)
Fathers	17	4 (24%)	6	1 (17%)
White UK	16	7 (44%)	5	2 (40%)
English primary language	17	14 (82%)	6	4 (67%)
PSS: PICU score	17	3.13 (2.43, 3.64)	6	3.12 (2.88, 3.26)
Children				
Age, years	17	6.00 (5.50, 10.50)	6	9.00 (5.50, 11.00)
Male	17	7 (41%)	6	3 (50%)
White UK	16	5 (31%)	6	3 (50%)
Length of stay in PICU, days	17	5.00 (4.00, 12.50)	6	6.00 (4.00, 9.50)
Length of stay in hospital, days	15	10.00 (6.00, 21.00)	5	7.00 (3.50, 17.00)
PIM2, %	17	4.10 (1.20, 7.68)	6	6.69 (4.33, 16.33)

Data are presented as median (inter-quartile range) or frequency (%).
PIM2 = Paediatric Index of Mortality 2
PSS:PICU = Parental Stressor Scale: Paediatric Intensive Care Unit

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Outcomes and estimations

Primary outcomes

Met and unmet outcomes together with suggested modifications/protocol amendments are outlined in Table 1.

Three out of six *intervention* feasibility and acceptability criteria were fully met: all parents said they had read the handbook, all evaluated it as useful, and most (82%) deemed it appropriately timed. Criteria not met included the time it took to execute both phases of the intervention, as well as the percentage of parents that engaged in the full intervention (although this was later reviewed as acceptable). Overall, the intervention was deemed feasible/acceptable with modifications.

In terms of the feasibility and acceptability of the *study design and procedures*, one criterion was fully met, namely families could be followed-up a median of five months post PICU discharge. Criteria not met included the number of eligible families admitted to PICU per month, the participation rate, the refusal rate (due to randomisation), the number lost to follow-up, and the time taken to return the baseline questionnaires. Thus, the study design and procedures were not deemed feasible/acceptable.

Additional comments collated from parents in the intervention group indicated that the information in the handbook made them feel more prepared for life after PICU (82%) and less anxious or concerned (77%). Almost half of the parents (47%) had shared the handbook with others including partners, relatives, their children (including the child admitted to PICU and their siblings), and teachers. With regards to the telephone call, 94% judged the timing to be good, 82% reported finding it useful, and 59% thought that a single call was sufficient (35% were unsure about this).

Secondary outcomes

Parent and child mental health outcomes are outlined in Table 3. Intervention parents reported fewer post-traumatic stress symptoms and depressive symptoms (small effect sizes), but there was little difference in anxiety scores (effect size <0.2). Table 3 shows that the children whose parents received the intervention had lower levels of total emotional and behavioural difficulties (moderate effect size), but there were negligible differences in sleep symptoms. Because of questionnaire age-range criteria and missing data, the IES-8 data are based on reduced total numbers and thus we will not comment on this data.

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Table 3. Mental health outcomes at 5 months post PICU discharge for families providing follow-up data in the intervention and treatment as usual groups

	n	Intervention group	n	Treatment as usual group	Effect size *d*[b]
Parent outcomes					
Impact of Events Scale:					
Post-traumatic symptoms total score	17	19.47 (11.64, 26.62)	6	25.83 (11.47, 39.00)	0.4
Hospital Anxiety and Depression Scale:					
Anxiety total score	17	6.47 (4.53, 8.54)	6	7.17 (4.20, 11.00)	0.2
Depression total score	17	2.76 (1.33, 4.45)	6	3.00 (0.00, 5.96)	0.1
Child outcomes					
Strength and Difficulties Questionnaire:					
Total Difficulties total score	14	9.21 (6.93, 11.31)	6	11.83 (6.50, 16.06)	0.6
Child Sleep Habits Questionnaire:					
Sleep disturbance total score	13	47.08 (42.72, 52.15)	6	48.00 (42.85, 52.83)	0.1
Impact of Events Scale-8[a]:					
Post-traumatic symptoms total score	3	13.00 (1.00, 20.00)	3	8.33 (0.00, 22.00)	-

Data are presented as means (BCa 95% CI) or frequency (%).

[a] The Impact of Events Scale-8 was the only child self-report measure used and could only be completed by children aged 8-16 years old, thus explaining the reduced ns.

[b] Effect sizes for continuous data are based on boostrapped SD. An effect size between 0.2 and 0.5 being considered a small effect, 0.5 and 0.8 a moderate effect, and 0.8 and above a large effect. An effect size was not calculated for the IES-8 data due to reduced ns.

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DISCUSSION

We report the results of a combined feasibility and pilot RCT of a novel supported psycho-educational intervention to help parents of children admitted to PICU recognise and manage possible psychological sequelae in themselves and their children. The results confirm the acceptability and feasibility of many aspects of the intervention, with clear indications of modifications that could be made to improve on this further. Although the study design and procedures were not deemed feasible, the data we gathered provided sufficient information to guide significant protocol amendments in order to ensure the overall feasibility of a future full efficacy trial. The comparison of mental health outcomes in the intervention and TAU groups five months following PICU discharge show the intervention to hold promise for reducing mental health difficulties in parents and their children.

Feasibility findings

Out of the twelve feasibility criteria developed *a priori* for the study, three out of six relating to the intervention and one out of six addressing the study design and procedures were fully met. All unmet criteria were reviewed and appropriate modifications to the intervention were formulated as well as more significant amendments to the study design and procedures, leading us to conclude that the revised protocol would be acceptable and feasible for a larger study. Changes include 1) obtaining consent, collecting baseline data, randomising, and delivering the psycho-educational tool whilst the child and their family are still on PICU (to help increase the participation rate, ensure baseline data are collected in a timely manner, and that the psycho-educational tool is delivered promptly); 2) a delay of the supportive telephone call to 3-6 weeks after PICU discharge (in line with a time-frame that was logistically viable and also considered acceptable by parents); 3) expanding the age range of children admitted into the study (to increase the number of eligible families); 4) reducing the number of assessment measures (to lessen the burden on participants and decrease the likelihood of attrition); and 5) working with patient and public involvement groups to provide a better explanation of the rationale for randomisation (to reduce non-participation on these grounds).

Notably, once parents were recruited to the study, it proved possible to provide the full intervention to 82%. This was initially considered an unmet criterion, as the target was 95%. Upon reflection, 82% was deemed acceptable, as this is a considerably higher rate than in previous studies offering outpatient consultations to families, where uptake in the intervention group ranged from 25% to 37% (6, 11). This suggests that providing after-care via a supported psycho-educational tool may be an effective way of increasing uptake of support in this difficult to reach population.

Secondary outcomes

Five months after PICU discharge, parents in the intervention group reported fewer post-traumatic stress symptoms and depressive symptoms than parents in the TAU group. Children of parents who received the intervention appeared to have fewer emotional and behavioural difficulties than those that received TAU. These differences were not subjected to statistical significance testing because our study was not powered to identify significant differences. Therefore, these findings need to be treated with caution and speculation about their meaningfulness is precluded. However, we believe the potential

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benefit of this supported psycho-educational intervention for parent and child mental health is worth exploring in a fully powered trial.

Strengths and limitations

Strengths of this study include its basis on empirical studies of PICU mental health outcomes, drawing and benefiting from the experience of previous well thought out, but ultimately unsuccessful intervention studies; the joint expert and lay approach to the development of the psycho-educational materials; the likely cost-effectiveness of the intervention; the careful approach to assessing feasibility and acceptability of both the intervention and study design/procedures. Limitations include falling short of the suggested minimum sample size for pilot studies; recruiting from a single centre, making generalisability uncertain; and the retrospective assessments of parental stress experienced whilst on PICU. As intended, however, the study opens the way for a future full RCT of the intervention.

Conclusion

Our study indicates that our novel intervention, a psycho-educational tool supported by a directed telephone call, is acceptable to parents. Although aspects of the intervention and study design/procedures were not deemed feasible, we were able to address each unmet criteria, putting protocol modifications/amendments in place. In addition, preliminary results indicate the potential beneficial effects of this supported psycho-educational tool for the mental health of parents and children. However, this needs to be subjected to a fully powered study before this intervention can be widely introduced into clinical practice.

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Competing interests

No, there are no competing interests.

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Contributors

All authors included on this paper fulfil the ICMJE criteria for authorship. All authors were involved in the study conception and design. LCA, SN, and MEG obtained the funding. LCA, SN, and MC recruited participants or collected and collated data. LCA analysed the data. All authors were involved in the interpretation of data. LCA and MEG drafted the article and SN, MC, and BV revised it critically for important intellectual content. All authors approved the final version of the work and agree to be accountable for all aspects of the work.

Ethical approval

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The NHS Research Ethics Committee at London Riverside approved the study.

Data sharing
No additional data are available.

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FIGURE LEGENDS

Figure 1. Participant flow chart

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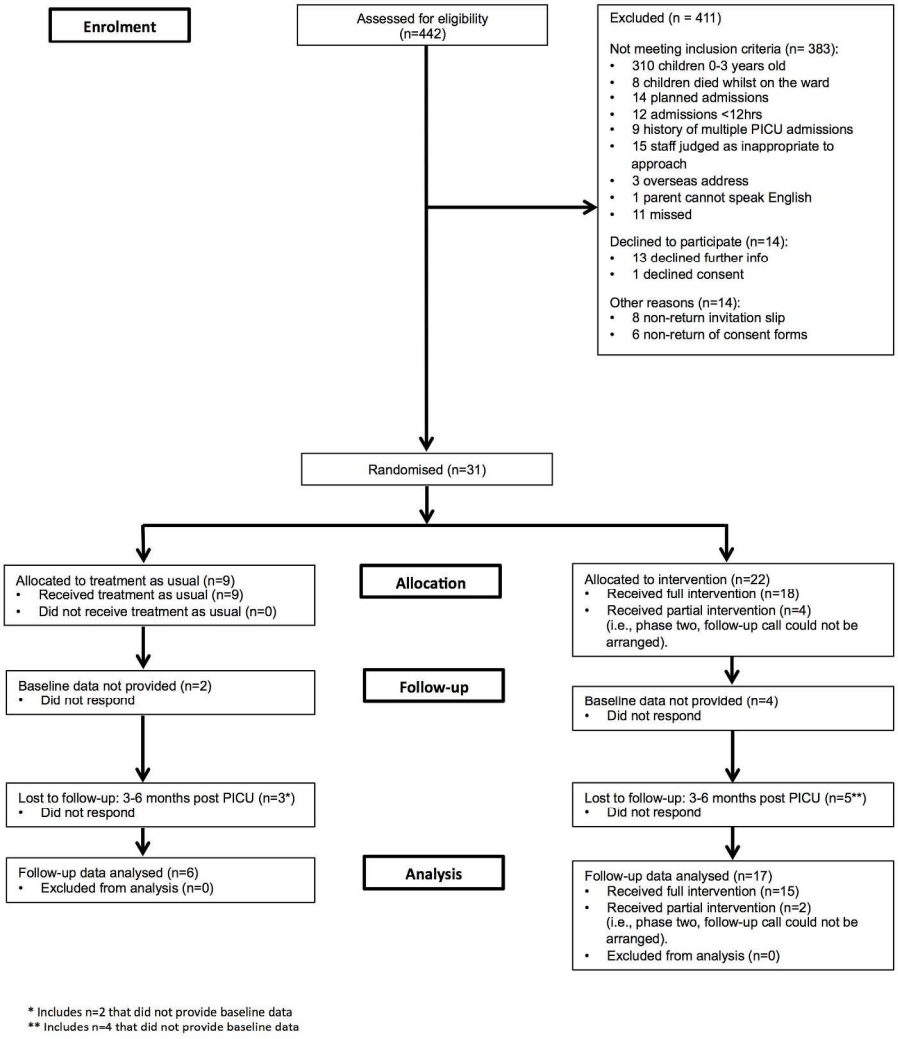

Figure 1. Participant flow chart
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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	8-9
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	7 & 12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13-14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-14
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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