Use of the Creating Opportunities for Parent Empowerment Program to Decrease Mental Health Problems in Ugandan Children Surviving Severe Malaria: A Randomized Controlled Trial

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Abstract

**Background:** Severe malaria is associated with long-term mental health problems in Ugandan children. This study investigated the effect of a behavioral intervention for caregivers of children admitted with severe malaria, on the children's mental health outcomes six months after discharge.

**Methods:** This randomized controlled trial was conducted at Naguru Hospital in Kampala, Uganda from January 2018 to July 2019. Caregiver and child dyads were randomly assigned to either a psychoeducation arm providing information about hospital procedures during admission (control group) or a behavioral arm providing information about the child's possible emotions and behavior during and after admission and providing age appropriate games for the caregiver and child (intervention group). Pre- and post-intervention assessments for caregiver anxiety and depression (Hopkins Symptom Checklist) and child mental health problems (Strength and Difficulties Questionnaire and the Child Behavioral Checklist) were done during admission and six months after discharge respectively. T-tests, analysis of covariance and Chi-Square were used to compare outcomes between the two treatment arms.

**Results:** There were 120 caregiver-child dyads recruited at baseline with children aged 1.45 years to 4.89 years (mean age 2.85 years, SD = 1.01). The intervention and control groups had similar sociodemographic, clinical and behavioral characteristics at baseline. Caregiver depression at baseline, mother's education and female sex of the child were associated with behavioral problems in the child at baseline (p<0.05). At six months follow-up, there was no difference in the frequency of behavioral problems between the groups (6.8% vs 10% in intervention vs. control groups, respectively, p = 0.72). Caregiver depression and anxiety scores between the treatment arms did not differ at six months follow-up.

**Conclusion:** This behavioral intervention for caregivers and their children admitted with severe malaria had no effect on the child's mental health outcomes at six months. Further studies need to develop interventions for mental health problems after severe malaria in children with longer follow-up time.

**ClinicalTrials.gov Identifier:** NCT03432039

Introduction

Malaria remains one of the leading causes of morbidity globally with 219 million cases reported in 2017 with over 90% in sub-Saharan Africa [1]. Some of these cases are severe leading to death especially in children under 5 years in Africa [1]. With more effective treatment for severe malaria, more children now survive from the disease than before [2]. Recent studies have shown that children surviving severe malaria have behavioral problems up to 24 months post discharge [3, 4]. Behavioral problems in childhood are associated with future psychiatric complications, challenges with education, employment and social life [5, 6]. In Ugandan children, behavioral problems after severe malaria maybe lead to harsh punishments from the caregivers as a way of making the child behave well [7].
Children admitted in intensive care units (ICU), like those with severe malaria, are exposed to stressors like invasive procedures, respiratory insufficiency, delirium with possible psychotic experiences, different professionals providing care and separation from families leading to mental health problems [8, 9]. As a result of this traumatic ICU experience, posttraumatic stress disorder (PTSD) is the commonest disorder in children followed by depression after admission for a life threatening illness [8]. Interventions aimed at preventing these psychological reactions after discharge should address the child and caregivers’ experiences of these stressors on the ward.

Creating Opportunities for Parent Empowerment (COPE) is an educational and behavioral intervention for children admitted in ICU and their caregivers to prevent adverse psychological reactions [10]. It creates a sense of control in the parent while on the ward through simple play activities that the parent and child can engage in and follows up the family after discharge to explain the likely post-discharge emotional problems and what parental behaviors can help to reduce these problems [10]. COPE postulates that information given to caregivers helps them anticipate what will occur on the ward and develop problem focused coping techniques to deal with the situation [10]. The activities through which the parent engages with the child instill feelings of control thus lessening anxiety. They also create an environment where negative emotions are controlled reducing the likelihood of transferring them to the child.

The present study evaluated the effect of this educational and behavioral intervention for caregivers and their children admitted with severe malaria. Caregivers and their children were assessed for mental health problems at baseline prior to the intervention and six months after discharge from hospital.

**Methods**

**Study design and participants**

This was a randomised controlled trial where children were assigned 1:1 to either a behavioural or educational treatment. Participants were children aged 1.5 years to 4 years. The inclusion criteria were; a) aged 1.5 to 4 years, b) admitted with severe malaria necessitating admission and intravenous anti-malarial medication, c) signed informed consent from the caregiver. Severe malaria in this study included; cerebral malaria, severe malarial anemia, malaria with impaired consciousness (but not in coma or cerebral malaria) and malaria with multiple seizures. The exclusion criteria were; a) living more than 50 km from the hospital, b) pre-existing developmental delays based on the Ten Questions Questionnaire [11].

**Study site**

The study was conducted at Naguru General Hospital in Kampala city, the capital of Uganda. This site was chosen because of its large catchment area which enabled the study to get a fairly representative sample of Kampala and its surroundings.

**Interventions**
Educational-behavioural intervention (experimental group)

This intervention was a modified version of the original COPE program [12]. This is an educational-behavioural intervention that educates the parent about the children's likely emotional and behavioural problems that may result from admission for a critical illness. It provides the parent with skills to deal with these problems and bring about a change in the child's behaviour as outlined below. This intervention (as well as the control intervention) was delivered by a graduate level psychologist who was not involved in assessment of the study outcomes. The COPE intervention was delivered in three phases with Phase I being delivered within 6 to 16 hours of admission to the hospital where caregivers were provided with information about the child's likely emotional reactions during admission in hospital (see supplementary materials; Intervention script). Phase II was delivered within 2 to 16 hours of transfer to the general ward and consisted of: (a) verbal and written information to reinforce information provided in Phase I plus additional information on children's responses during and following hospitalization, as well as to provide caregivers with further suggestions to enhance coping outcomes in their children, and (b) parent-child skills building activities. This consisted of three activities to be completed before discharge from the hospital; i) doll play to encourage expression of emotions in a nonthreatening manner, ii) therapeutic medical play to assist children in obtaining some sense of mastery and control over the hospital experience, and iii) telling a story about a young child who successfully copes with a stressful hospital admission. Parents were encouraged to engage their children in these games thereafter during admission. The modification in this study involved removing the audio taped instructions from Phases I and II, as done in the original study, and having the intervention instead delivered face-to-face [12].

Phase III of the educational-behavioural intervention program occurred 2 to 3 days after hospital discharge and consisted of a telephone call during which a 5 minute script was read that reinforced the following: (a) young children's typical post-discharge emotions and behaviours, and (b) parenting behaviours which would continue to facilitate positive coping outcomes in their children. Mothers were encouraged to continue performing the activities from Phase II that they received during hospitalization.

Psychoeducation intervention (control group)

This intervention also had three phases occurring the same time as the education-behavioural intervention [12]. Phase I provided verbal and written information about the pediatric admission unit services and policies. Phase II consisted of: (a) verbal and written information about the general pediatric unit and its policies, and (b) a parent-child activity having "control" activities like reading a story not related to hospital stay. Phase III of the control program consisted of a telephone call 2–3 days after discharge during which time mothers were informed that they should contact their primary healthcare providers if their children were having any problems or unusual symptoms. They also were asked to comment on their children's hospital stays during this telephone call (see supplementary materials; control script).

The games and stories of the interventions were different for the age groups. The hospital in which the study was conducted has an open general ward for children which made it impossible to separate
participants from the different arms while on the ward to prevent them from observing different games
and activities of the other intervention.

Outcomes

Primary and secondary outcomes were assessed during admission prior to the intervention and at 6
months after discharge. Presence of a behavioural problem was the primary outcome of the study which
was assessed using the self report Strengths and Difficulties Questionnaire (SDQ) [13, 14]. It has 25 items
assessing five domains of five items each; emotional, conduct, hyperactivity, peer and prosocial
problems. Summation of scores from the first four scales gives the total difficulties score which will be
the primary outcome measure for the SDQ [14]. The SDQ has been used in Uganda to screen for
behavioural problems, including a study on children with severe malaria [3, 15, 16]. A score of 17 or more
was indicative of behavioural problems.

Total behavioural problems score in the children assessed using the preschool CBCL version was a
secondary outcome of the study. The CBCL has 100 items about the child's behaviour that the parent
responds to which can be summarised into seven subscales which are further summarised into
Externalising, Internalising and Total Problems [17]. The CBCL has been used in several studies in
Uganda and is reliable in assessing behaviour over time [4, 18]. It was included to supplement the SDQ
given its broad assessment of behavioural problems using its widely used syndrome scales [19].

Maternal depression and anxiety were other secondary outcomes which were assessed using the Hopkins
Symptom Checklist (HSCL). Anxiety and depression are common outcomes in parents whose children
have been in ICU [20]. It has 25 items with the first 10 items assessing anxiety and the next 15 assessing
depression. It is a reliable and valid measure for anxiety and depression in Ugandan adults [21].

A socioeconomic status form used in previous studies in Uganda was used to measure the material
possessions of the family, housing type, cooking resources and water source [22, 23]. These were scored
and summed up to get a socioeconomic status score. The Ten Questions Questionnaire [11, 24] was used
to screen for children with neurodevelopmental delay who could have pre-existing behavioural problems
that would confound the intervention outcomes. It is a widely used screen for neurodevelopmental
disabilities and has been used in a field survey of neurodevelopmental disabilities in Uganda [25].

Sample size estimation

In the original COPE trial, an absolute difference of 23.6% in the prevalence of behavioural problems
between the control and COPE arms (25.9% vs 2.3% respectively) was observed 12 months after the
intervention [12]. In the proposed study, the 6 month assessment was the primary endpoint. Assuming the
COPE arm to have 2.3% with behavioural problems [12] and the control arm would have to the same rate
as observed in Idro et al (18.5%) [3], a sample size of 55 per group was needed to for a study powered at
80%. Assuming a loss to follow-up of 10%, 60 children per arm were targeted for enrolment.

Randomization procedure
Stratified randomisation was done by age groups, i.e. 1 year age band, 2 year age band, 3 year age band and 4 year age band were randomised individually. For each of these age groups, random numbers were computer generated by the first author and the treatment allocation kept in sealed opaque envelopes that were serially numbered to conceal allocation. The psychologist administering the intervention had custody of these envelopes which she opened to reveal the treatment group once a participant was enrolled by the study nurse. Assessors of the child’s mental health were blinded to the child’s treatment arm allocation by not involving them in the providing the intervention or access to the group allocation envelopes. not being pre. Caregivers were also blinded to the child’s treatment allocation, however because it was impossible to separate them on the ward, there is a possibility they may have observed different interventions being given to other children.

Data management and analysis

Data was entered into FileMaker with validation checks and exported to IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA) for analysis. The Chi squares test was used to compare the rates of children with a behavioural problem between the two groups. T-tests were used to compare continuous scores between the study groups. Analysis of covariance controlling for maternal anxiety and child’s sex was used to compare 6 month behavioural problems of the children in the treatment arms.

Results

Participant recruitment

One hundred and twenty participants were recruited into the study from January 2018 to November 2018 and followed up 6 months later from June 2018 to July 2019. Sixty were assigned to the control arm of which 55 received the intervention and 50 were analysed for the primary outcome. Sixty were assigned to the intervention arm, 49 received the intervention and 45 were analysed for the primary outcome. The study profile (Fig. 1) provides details of the numbers that were excluded leading to the final numbers assessed. The study concluded when the last participant who could be located was assessed after 6 months.

Baseline characteristics of the study participants

The mean age of the children was 2.85 years (SD = 1.10) with 51.7% female. Children in both treatment arms had similar sociodemographic, clinical and behavioural characteristics (Table 1). Baseline behavioural problems in children were associated with caregiver depression, caregiver education and child’s sex (Table 2). Caregiver’s anxiety and depression at baseline during admission were associated with presence of diarrhoea and behavioural problems in the child.
| Characteristic                      | Intervention (n = 59) | Control (n = 59) | P value |
|------------------------------------|-----------------------|------------------|---------|
| Age, years                         | 2.85 (1.01)           | 2.84 (1.03)      | 0.96    |
| Sex, female (n, %)                 | 31 (52.5%)            | 30 (50.8%)       | 0.85    |
| Socioeconomic status score         | 11.75 (3.73)          | 12.85 (2.81)     | 0.08    |
| Child in school (n, %)             | 15 (26.3%)            | 17 (28.8%)       | 0.76    |
| Mother’s education (n, %)          |                      |                  | 0.85    |
| None                               | 2 (3.6%)              | 4 (7.0%)         |         |
| Primary                            | 23 (41.8%)            | 22 (38.6%)       |         |
| Secondary                          | 27 (49.1)             | 27 (47.4%)       |         |
| Tertiary                           | 3 (5.5%)              | 4 (7.0%)         |         |
| Mother’s education (n, %)          |                      |                  | 0.19    |
| None                               | 1 (1.9%)              | 1 (1.8%)         |         |
| Primary                            | 16 (29.6%)            | 13 (22.8%)       |         |
| Secondary                          | 26 (48.1%)            | 38 (66.7%)       |         |
| Tertiary                           | 11 (20.4%)            | 5 (8.8%)         |         |
| Weight for age z score             | -0.80 (1.07)          | -0.56 (1.06)     | 0.22    |
| Temperature, °C                    | 38.56 (1.23)          | 38.66 (0.88)     | 0.61    |
| Days with fever                    | 4.88 (3.55)           | 4.72 (3.73)      | 0.81    |
| Coughing (n, %)                    | 35 (59.3%)            | 40 (69.0%)       | 0.28    |
| Difficulty breathing (n, %)        | 12 (20.3%)            | 6 (10.3%)        | 0.13    |
| Diarrhea (n, %)                    | 14 (23.7%)            | 18 (31.0%)       | 0.38    |
| Vomiting (n, %)                    | 29 (49.2%)            | 26 (44.8%)       | 0.64    |
| Convulsions (n, %)                 | 20 (33.9%)            | 15 (26.3%)       | 0.37    |
| Last fed, hours                    | 26.72 (30.56)         | 22.69 (28.32)    | 0.48    |
| Last drank, hours                  | 3.09 (7.86)           | 2.40 (2.89)      | 0.56    |
| Respiratory rate                   | 38.70 (12.96)         | 34.58 (12.51)    | 0.24    |

All figures are Mean (standard deviation) unless otherwise stated. Frequencies compared with Chi squared testing. Continuous values compared with Students t-test.
| Characteristic                        | Intervention (n = 59) | Control (n = 59) | P value |
|--------------------------------------|-----------------------|------------------|---------|
| SDQ Behavioral problem in the child (n, %) | 23 (40.4%)            | 20 (33.9%)       | 0.47    |
| SDQ Total score                      | 15.47 (5.18)          | 15.56 (4.57)     | 0.93    |
| CBLC Total problems                  | -0.83 (0.82)          | -0.91 (0.83)     | 0.58    |
| CBLC Internalizing problems          | -1.08 (0.640)         | -1.12 (0.66)     | 0.73    |
| CBLC Externalizing problems          | -1.19 (0.58)          | -1.27 (0.66)     | 0.51    |
| HSCL Caregiver anxiety score         | 5.75 (5.49)           | 6.00 (6.17)      | 0.82    |
| HSCL Caregiver depression score      | 12.72 (9.39)          | 12.64 (9.70)     | 0.97    |

All figures are Mean (standard deviation) unless otherwise stated. Frequencies compared with Chi squared testing. Continuous values compared with Students t-test.
Table 2
Risk factors for behavioral problems in children at baseline

| Characteristic                          | Behavioral problem\(^1\) (n = 43) | No behavioral problem (n = 73) | P value |
|----------------------------------------|------------------------------------|--------------------------------|---------|
| Age, years                             | 2.82 (1.03)                        | 2.88 (1.02)                    | 0.79    |
| Sex, female (n, %)                     | 27 (62.8%)                         | 32 (43.8%)                     | 0.05    |
| Socioeconomic status score             | 12.47 (3.32)                       | 12.22 (3.35)                   | 0.70    |
| Child in school (n, %)                 | 11 (25.6%)                         | 21 (28.8%)                     | 0.71    |
| Mother’s education (n, %)              |                                    |                                | 0.05    |
| None                                   | 2 (4.9%)                           | 4 (5.6%)                       |         |
| Primary                                | 22 (53.7%)                         | 23 (32.4%)                     |         |
| Secondary                              | 13 (31.7%)                         | 41 (57.7%)                     |         |
| Tertiary                               | 4 (9.8%)                           | 3 (4.2%)                       |         |
| Weight for age z score                 | -0.80 (1.12)                       | -0.62 (1.03)                   | 0.38    |
| Temperature, °C                        | 38.77 (1.04)                       | 38.50 (1.08)                   | 0.19    |
| Days with fever                        | 4.67 (3.13)                        | 4.93 (3.91)                    | 0.71    |
| Coughing (n, %)                        | 28 (66.7%)                         | 46 (63.0%)                     | 0.69    |
| Difficulty breathing (n, %)            | 7 (16.7%)                          | 11 (15.1%)                     | 0.82    |
| Diarrhea (n, %)                        | 15 (35.7%)                         | 17 (23.3%)                     | 0.15    |
| Vomiting (n, %)                        | 21 (50.0%)                         | 34 (46.6%)                     | 0.72    |
| Convulsions (n, %)                     | 11 (26.2%)                         | 22 (30.6%)                     | 0.62    |
| Last fed, hours                        | 25.03 (30.20)                      | 24.12 (28.85)                  | 0.88    |
| Last drank, hours                      | 2.00 (2.09)                        | 3.10 (6.80)                    | 0.41    |

All figures are Mean (standard deviation) unless otherwise stated. Frequencies compared with Chi squared testing. Continuous values compared with Students t-test. \(^1\)An SDQ score ≥ 17.
| Characteristic                  | Behavioral problem<sup>1</sup> (n = 43) | No behavioral problem (n = 73) | P value |
|--------------------------------|----------------------------------------|-------------------------------|---------|
| Respiratory rate               | 40.24 (14.94)                          | 34.23 (10.94)                 | 0.10    |
| Caregiver anxiety score        | 7.12 (6.30)                            | 5.15 (5.44)                   | 0.08    |
| Caregiver depression score     | 15.40 (10.62)                          | 11.08 (8.47)                  | **0.02**|

All figures are Mean (standard deviation) unless otherwise stated. Frequencies compared with Chi squared testing. Continuous values compared with Students t-test. <sup>1</sup>An SDQ score ≥ 17.

**Child and caregiver behavioural outcomes at 6 months follow-up**

The frequency of behavioural problems in the intervention arm (6.8%) vs the control arm (10%) was not different (relative risk 0.66, 95% CI 0.15 to 2.93, p = 0.72). There were no differences between the treatment arms in the secondary from both the SDQ and CBCL at 6 months follow-up after controlling for baseline caregiver depression, and education level (Table 3). Similarly, there were no differences in caregiver anxiety and depression outcomes at 6 months after controlling for presence of diarrhoea and behavioural problems in the child.
Table 3
Child and caregiver emotional and behavioral outcomes at six months

| Domain                              | Intervention (n = 45) | Control (n = 50) | Mean difference (95% CI) | P value |
|-------------------------------------|-----------------------|------------------|--------------------------|---------|
| Behavioral problem in the child (n, %) | 3 (6.8%)              | 5 (10.0%)        | -0.72                   |         |
| SDQ Total problems                  | 10.26 (0.71)          | 10.69 (0.66)     | -0.43 (-2.35 to 1.50)   | 0.661   |
| SDQ Emotional problems              | 2.23 (0.29)           | 2.22 (0.27)      | 0.01 (-0.79 to 0.81)    | 0.991   |
| SDQ Conduct problems                | 2.21 (0.29)           | 2.98 (0.27)      | -0.77 (-1.55 to 0.01)   | 0.0541  |
| SDQ Hyperactivity problems          | 3.99 (0.29)           | 3.76 (0.27)      | 0.22 (-0.57 to 1.02)    | 0.581   |
| SDQ Peer problems                   | 1.84 (0.22)           | 1.72 (0.20)      | 0.12 (-0.47 to 0.70)    | 0.701   |
| SDQ Prosocial problems              | 7.78 (0.25)           | 8.15 (0.24)      | -0.37 (-1.06 to 0.32)   | 0.291   |
| CBCL Total Problems                 | -1.38 (0.12)          | -1.32 (0.12)     | -0.06 (-0.39 to 0.27)   | 0.741   |
| CBCL Internalizing Problems         | -1.20 (0.10)          | -1.20 (0.10)     | 0.002 (-0.27 to 0.28)   | 0.991   |
| CBCL Externalizing Problems         | -1.35 (0.12)          | -1.17 (0.11)     | -0.18 (-0.50 to 0.14)   | 0.261   |
| HSCL Caregiver anxiety              | 2.94 (0.69)           | 4.51 (0.66)      | -1.57 (-3.46 to 0.32)   | 0.102   |
| HSCL Caregiver depression           | 8.85 (1.14)           | 9.24 (1.09)      | -0.38 (-3.53 to 2.77)   | 0.812   |

All figures are Mean (standard error) unless otherwise stated. Frequencies compared with Fisher’s exact test. Continuous values compared with Students t-test.

1 Adjusted for caregiver depression, mother’s education and child’s sex

2 Adjusted for presence of diarrhea and behavioral problems for the child during admission.

Discussion

This study set out to examine the effect of a care-giver behavioural intervention for children admitted with severe malaria to prevent mental health problems 6 months after discharge. There were no differences in mental health outcomes between the two groups after 6 months. Mental health problems in the children during admission were associated with caregiver depression, caregiver education and the child’s sex.

Admission for children in hospitals can be a stressful experience and is associated with anxiety and depression in caregivers and children in both the acute period of the disease and in the long-term period [8, 9]. Ugandan children with severe malaria have mental health problems in both the short and long-term that include hyperactivity, aggression and mood changes [3, 4]. Studies show that mental health
problems in children admitted in hospital are associated with illness severity, duration of admission and premorbid mental health problems [26, 27]. In the present study, only caregiver depression, caregiver education and child’s sex were associated with the child’s mental health problems during admission. However disease severity in terms of having diarrhoea during admission was associated with caregiver anxiety and depression scores. Caregivers of admitted children feel out of control, leading to anxiety which can be transferred on the child who sees the caregiver in that state [10]. The present study found a correlation between caregivers’ anxiety and depression scores and the child’s mental health scores which is in line with the emotional contagion theory [10].

The present study’s intervention is based on the above premise that there is an association between caregiver and the child’s mental health during admission. Thus targeting behavioural problems in the caregiver by providing information about the admission (to create a feeling of control) and creating avenues for playful interaction between the caregiver and child (to reduce anxiety associated with admission) is a possible avenue to prevent mental health problems in children after admission for severe malaria. In this study however, the intervention was not associated with improved mental health outcomes in the children six months after discharge. The same intervention has been used in children admitted in intensive care and was associated with less mental health problems in the children and their caregivers [10, 12]. Some effects were observed at six months, while others were observed at twelve months. The six month follow-up in our study may have been too short to observe any effect. Alternatively, an intervention developed for children in a US intensive care unit setting may not translate into an effective intervention for the very different and more resource-limited hospital setting for severe illness in a Uganda hospital, even with adaptation for the Ugandan context.

The evaluation of behaviour was also different, with the present study using the SDQ (primary) and the CBCL (secondary), while the US intensive care unit study used the Behavior Assessment System for Children (BASC) [12]. The SDQ assesses primarily emotional, conduct, hyperactivity, peer and prosocial problems, while the BASC version they used evaluates externalizing problems, internalizing problems, behavioral symptoms, and adaptive skills [12]. Differences in areas being evaluated may have contributed to the differences in study findings, and future studies may need to assess adaptive skills that are tested in BASC but not the SDQ. In addition, in the study of COPE in US ICUs, the BASC scores for the control group were variable over time and increased (more behavioural problems) substantially from 6 months to 12 months. This could reflect variability in response to a questionnaire over time, or might reflect increased behavioural problems 12 months after illness. If the latter was the primary driver for differences, then testing at 12 months in this cohort may have revealed problems not found at 6-month follow-up. Finally, malaria is uncommon in the US, and it is unlikely that any child had malaria (11% in Melnyk et al were admitted for infections like sepsis and meningitis). Diseases can affect behaviour in different ways, so it is possible that the COPE intervention is less effective for children with severe malaria. Countering this is that children in the US COPE ICU study were admitted with many different underlying diagnoses, yet appeared to have a benefit at 12 months after their illness from the COPE intervention. The COPE intervention has been used in other populations, including premature neonates [28] and children with neurological problems [29], with some success in improved mental health for the
caregiver, child or both, so it will be important to determine if in longer-term follow-up better outcomes are seen with the intervention in children with severe malaria.

The study's inability to completely conceal the interventions participants received on the ward may have resulted in bias as caregivers rated behavioural problems of their children and their own. Children in the intervention received different play activities from the control group. This bias in reporting may have affected the intervention resulting in no differences in outcomes between the groups.

The present study was limited by its short follow-up duration of six months which could have resulted in no effect seen at that time point. Additionally, there was a higher rate of loss to follow-up in the intervention arm leading to a smaller sample size that limited the power of the study. It was not possible to separate participants from the different treatment arms on the ward which may have led to caregivers noticing different interventions being given to their child. The strengths of the study include its randomised design and blinding of the assessors that limits bias in assessing the outcomes.

This study's behavioural intervention had no effect on children's mental health problems six months after discharge. There is need to identify other behavioural interventions that could improve mental health outcomes for children admitted in this setting. A prior study in Uganda identified neurologic deficits and seizures during admission as being associated with these behavioural problems [3]. Thus, in addition to behavioural interventions, adjunctive therapies to improve outcome after severe malaria may potentially lead to improved mental health outcomes, and could supplement behavioural interventions as this one [30].

**Abbreviations**

BASC: Behavior Assessment System for Children

CBCL: Child behaviour checklist

COPE: Creating Opportunities for Parent Empowerment

HSCL: Hopkins Symptom Checklist

ICU: Intensive care unit

PTSD: Posttraumatic stress disorder

SDQ: Strengths and Difficulties Questionnaire

**Declarations**

*Ethics approval and consent to participate*
The study was approved by the Makerere University School of Medicine Research and Ethics Committee (REC 2017-088) and the Uganda National Council for Science and Technology. All participants provided written informed consent. The study is registered at clinicaltrials.gov (NCT03432039).

**Consent for publication**

Not applicable.

**Availability of data and materials**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Competing interests**

The authors declare that they have no competing interest.

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**Authors’ contributions**

PB conceived the study and analysed the data. PB, MN, AJN developed the study intervention materials. PB, AB, MN, AJN participated in the conduct of the study. All authors contributed to the writing of the manuscript, interpretation of the findings, read and approved the final manuscript.

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Figures
Figure 1

Study Flow Diagram

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• NURTUREinterventionscript.docx
• NURTUREcontrolscript.docx
• NURTURECONSORTchecklist.docx