

Original Article

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Psychological treatments delivered by community health workers in low-resource government health systems: effectiveness of group interpersonal psychotherapy for caregivers of children affected by nodding syndrome in Uganda

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Background. Despite increasing evidence for the benefits of psychological treatments (PTs) in low- and middle-income countries, few national health systems have adopted PTs as standard care. We aimed to evaluate the effectiveness of a group interpersonal psychotherapy (IPT-G) intervention, when delivered by lay community health workers (LCHWs) in a low-resource government health system in Uganda. The intended outcome was reduction of depression among caregivers of children with nodding syndrome, a neuropsychiatric condition with high morbidity, mortality and social stigma.

Methods. A non-randomized trial design was used. Caregivers in six villages ($n = 69$) received treatment as usual (TAU), according to government guidelines. Caregivers in seven villages ($n = 73$) received TAU as well as 12 sessions of IPT-G delivered by LCHWs. Primary outcomes were caregiver and child depression assessed at 1 and 6 months post-intervention.

Results. Caregivers who received IPT-G had a significantly greater reduction in the risk of depression from baseline to 1 month [risk ratio (RR) 0.25, 95% confidence interval (CI) 0.10–0.62] and 6 months (RR 0.33, 95% CI 0.11–0.95) post-intervention compared with caregivers who received TAU. Children of caregivers who received IPT-G had significantly greater reduction in depression scores than children of TAU caregivers at 1 month (Cohen's $d = 0.57$, $p = 0.01$) and 6 months (Cohen's $d = 0.54$, $p = 0.03$). Significant effects were also observed for psychological distress, stigma and social support among caregivers.

Conclusion. IPT-G delivered within a low-resource health system is an effective PT for common mental health problems in caregivers of children with a severe neuropsychiatric condition and has psychological benefits for the children as well. This supports national health policy initiatives to integrate PTs into primary health care services in Uganda.

Introduction

The implementation of evidence-based interventions for mental, neurological and substance use (MNS) disorders can reduce the substantial treatment gap in low- and middle-income countries (LMICs), where up to 90% of those in need do not have access to mental health services (Whiteford *et al.* 2013; Wainberg *et al.* 2017) and only 4–11% of persons with depression receive minimally adequate care (Thorncroft *et al.* 2017). The use of non-specialist health workers to deliver mental health treatments is a crucial component of reducing this treatment gap (Singla *et al.* 2017; Wainberg *et al.* 2017). This strategy is referred to as a 'task-shifting' or 'task-sharing' approach, in which components of traditionally specialized health care are delegated to existing or new cadres with either less training or narrowly tailored training for the required service (Fulton *et al.* 2011).

The World Health Organization (WHO) mental health Global Action Programme (mhGAP) (World Health Organization, 2016) and Disease Control Priorities network project (Patel *et al.* 2016) recommend that psychological treatments (PTs) be integrated into primary care and community services through task-sharing approaches. Despite this evidence, the use

of lay community health workers (LCHWs) for the provision of mental health services in LMICs is not widespread and varies considerably across countries.

In Uganda, there is a unique opportunity to advance integration of PTs into the public health system because of an existing policy environment. The national health policy includes mental health as one of 12 components of the National Minimum Health Care Package to be provided at all levels of care (Kigozi *et al.* 2010). Following recommendations from the WHO, the Uganda Ministry of Health recently took steps to scale-up the provision of evidence-based PTs within primary care. LCHWs form the first tier of the health system in Uganda but their involvement to date in MNS programming is lacking (Kigozi *et al.* 2010; Bazos *et al.* 2015). Randomized controlled trials of PTs in Uganda indicated that group interpersonal psychotherapy (IPT-G), a WHO recommended treatment, had demonstrated effectiveness in the treatment of mental disorders when delivered by trained LCHWs (Bolton *et al.* 2003, 2007). However, these treatments were provided outside the government health system and delivered by paid non-governmental organization (NGO) staff who had high levels of supervision and support from mental health experts in high-income countries. There is a lack of studies demonstrating the effectiveness of PTs delivered by LCHWs in the Uganda government health system.

The objective of this study was to demonstrate that LCHWs within the government health system could effectively deliver a PT. The intended beneficiaries were caregivers and their children with nodding syndrome (NS), an unexplained neuropsychiatric disorder similar to epilepsy that afflicts more than 3000 children and adolescents in northern Uganda (Idro *et al.* 2013, 2016). NS is characterized by head nodding episodes, epileptic seizures, mental and physical deterioration (Idro *et al.* 2013). The cause is unknown; however, there is a strong epidemiological association with onchocerciasis (Idro *et al.* 2016; Johnson *et al.* 2017). The burden of NS is exacerbated by frequent co-occurrence of common mental health problems in both the affected child and his/her caregiver. A post-conflict setting in northern Uganda and substantial stigma serve as additional contextual risk factors for poor mental health (Idro *et al.* 2013; Buchmann, 2014; Mutamba *et al.* 2014; Mwaka *et al.* 2015; Nakigudde *et al.* 2016). Not only do depression and post-traumatic stress disorder (PTSD) remain prevalent in northern Uganda (Roberts *et al.* 2008; Mugisha *et al.* 2015a, d), but caregivers to children with neuropsychiatric disorders have been found to have high levels of psychiatric morbidity (Okewole *et al.* 2011). Caregiver mental health – by influencing factors such as connectedness, access to services and availability of social support – mediates child mental health and behavioural outcomes (Elbedour *et al.* 1993; Beardseele *et al.* 1998; Betancourt, 2011; Betancourt *et al.* 2012). Relatedly, parent-mediated interventions have shown evidence for improving mental health of the ill child (Rahman *et al.* 2008; Shaw *et al.* 2009; Stadnick *et al.* 2015) highlighting the key role of caregiver treatments in child and adolescent mental health interventions (Morris *et al.* 2011).

This study coincided with the roll-out of Uganda national management guidelines for NS, which advise a multidisciplinary treatment approach including psychosocial support for families affected by the disorder (Idro *et al.* 2013). The guidelines do not include, however, recommendations or protocols for PTs. Therefore, evaluation and subsequent implementation of a community psychosocial intervention using a task-shifting approach has potential to complement the government health response to

NS and expand the evidence base for potential nationwide psychological services in government health care.

Method

This study was a non-randomized trial with caregivers in a control arm receiving treatment as usual (TAU) and caregivers in an experimental arm receiving IPT-G in addition to TAU. We employed a quasi-experimental design that ‘takes advantage of unplanned events to assess the impact of an exposure or an intervention on a well-defined group of people who happened to be affected by that event and where randomization may not be practical’ (Ford, 2003). A randomized trial was not considered feasible due to: restriction by the government to conduct the intervention in a particular area; the group format of the intervention; a high probability of contamination of intervention effects between IPT-G and ongoing NS psychosocial programmes by other agencies within the study district; and the diffuse social nature of stigma against NS. The study was conducted over a period of 18 months in northern Uganda between April 2013 and September 2014.

We obtained approval for the study from the Makerere University College of Health Sciences, School of Public Health Higher Degrees, Research and Ethics Committee, and the Uganda National Council of Science and Technology. Informed consent was obtained from all the participants after the purpose, procedures, risk and benefits of the study were explained. The trial was retrospectively registered (ISRCTN11382067; registration date: 6 June 2016).

Study participants and procedures

Thirteen villages in northern Uganda were selected for inclusion in the study. Using health facility (HF) records, seven villages were assigned to the IPT-G condition and six villages were assigned to TAU based on the number of families affected in a village. Caregivers were recruited by LCHWs referred to as village health team members (VHTs). A caregiver was included in the study if she/or he was an adult (≥ 18 years of age) living in the selected study villages, was a primary caregiver for a child with NS and willingly provided informed written consent. A child was included if they had NS and a consenting caregiver with them. In families with more than one child with NS (approximately 30%), caregivers were asked to identify one of their children most affected by NS that would participate in the study. Following consent by the caregiver, trained health workers conducted assessments and recorded baseline demographic and outcome measures from both caregivers and children.

Study intervention

Group interpersonal psychotherapy

We used the Replicating Effective Programs (REP) framework (Kilbourne *et al.* 2007) to identify, adapt, implement and evaluate an appropriate intervention. IPT-G was selected as the PT of choice because it is a WHO-endorsed psychosocial intervention for LMICs (World Health Organization, 2016) and has an evidence base of prior randomized controlled trials conducted in Uganda (Bolton *et al.* 2003, 2007).

Interpersonal psychotherapy (IPT) is a brief attachment-focused PT that was initially designed to treat depressive symptoms by improving interpersonal functioning and social support

(Klerman *et al.* 1984; Weissman *et al.* 2000). It was originally developed as an individual therapy but can be delivered in group format (Bolton *et al.* 2003, 2007; Petersen *et al.* 2012). IPT involves the therapist and client conceptualizing the patient's difficulties in relation to the patient's key relationships and focusing on one of four problem areas: interpersonal dispute, grief and loss, role transitions and interpersonal sensitivity (Weissman *et al.* 2000). In a meta-analysis of 90 IPT studies, including 22 that used group format, the therapy had a moderate to large effect size ($g = 0.60$; 95% confidence interval (CI) = 0.45–0.75) for acute-phase depression and there is no evidence that it is less effective than cognitive behaviour therapy and other PTs (Cuijpers *et al.* 2016).

Table 1 provides an overview of the implementation adaptations to make delivery feasible in government health services.

Caregivers in the intervention villages received 12 weekly 90–120 min IPT-G sessions in addition to usual care for NS (see TAU description below). IPT-G sessions were of mixed-gender and consisted of 10–16 individuals per group. Group sessions were held at jointly agreed meeting places in the community and delivered by IPT-G trained LCHWs. A 7-day training for LCHWs was led by IPT experts in Uganda who had previously participated in NGO delivery of IPT (Bolton *et al.* 2003, 2007). Supervision was conducted by government health workers who attended the same training. Both the LCHWs and primary health workers attended a weekly, joint supervision meeting facilitated by the IPT-G experts.

Treatment as usual

All health workers at HFs in the study sites received training on the medical management of children with NS. Caregivers in the TAU and experimental-arm villages received usual care as provided for in the national management guidelines for NS (Idro *et al.* 2013). TAU included health education about NS, syndromic management of children with pharmacological agents (typically sodium valproate or carbamazepine), caregiver education and supportive counselling (Idro *et al.* 2013). The LCHWs received separate training on community case identification and health promotion for NS, provided by government health workers.

Instruments

All caregivers completed a battery of instruments at three time points: baseline, 1 month post-treatment and 6 months post-treatment. Interviews were conducted in-person by trained research assistants and lasted an average of 45 min. Caregivers completed a battery of mental health and psychosocial instruments for one index child with NS. Older children of at least 10 years of age and adolescents (more than 80% in both arms) were encouraged to participate in the interview process to provide additional details when caregivers lacked information or were unaware of specific mental health complaints. Training of research assistants in the application of the different study instruments was done by a psychiatrist fluent in Luo – the local language spoken by participants. All instruments were translated from English to Luo and back-translated and piloted. The study instrument included the following battery of assessments:

Caregiver outcomes

Depression, generalized anxiety disorder (GAD), PTSD and suicide risk assessment were measured using the MINI Neuropsychiatric interview (Version 5.0) (Sheehan *et al.* 1998). The MINI has been used in several Ugandan populations (Abbo *et al.* 2009; Kinyanda *et al.* 2011) including Luo (Nakimuli-Mpungu *et al.* 2015; Mugisha *et al.* 2015b, c).

Psychological distress was assessed using the Self Report Questionnaire (SRQ-20). The instrument has been validated and widely used in Uganda (Nakigudde *et al.* 2005; Nakimuli-Mpungu *et al.* 2013) with high internal reliability of $\alpha = 0.97$ in a similar study population (Nakimuli-Mpungu *et al.* 2013).

Functional impairment was assessed using the Assessment of Functioning questionnaire, a locally developed dimensional tool with a Cronbach α of 0.71 in this population. The scale consists of five categories of tasks including household (e.g. washing clothes), field (e.g. grazing animals), social (e.g. attending social events) and job-related or school-related tasks (e.g. participating in income-generating activities, attending school) and tasks

Table 1. Adaptations of group interpersonal therapy (IPT-G) for delivery in government health systems

	Prior implementation of IPT-G by non-governmental organizations (NGO) in Uganda (Bolton <i>et al.</i> 2003, 2007, Verdelli <i>et al.</i> 2003, 2008)	Adaptations for IPT-G in Uganda government health system
Setting	Rural communities and internally displaced camps in southwest and northern Uganda	Rural communities in northern Uganda
Delivery agent	Compensated NGO workers with English-language proficiency and literacy without prior health training	Volunteer government community health workers without literacy requirements and with prior 2–5 days training in basic physical health prevention and promotion
Training	13–14 days training delivered by high-income country psychologists with expertise in IPT	7 days initial training plus 2-day refresher training delivered by Ugandan IPT-G experts
Supervision	Delivered in person by high-income country psychologist with expertise in IPT	Delivered by primary health workers working at government health facilities with no prior training in IPT, in conjunction with IPT-G experts and a clinical psychologist from Uganda
Beneficiaries	Community members living with HIV/AIDs in southwest Uganda and survivors of political violence in northern Uganda	Survivors of political violence with children affected by NS in northern Uganda
Content of IPT-G	Culturally adapted IPT-G, with removal of 'interpersonal deficits' component for the adult intervention but retained for adolescents	Same content as NGO version with revision to address VHT needs, and addition of NS-specific content
Duration of IPT-G	16 weekly 90–120 min sessions	12 weekly 90–120 min sessions

related to personal hygiene (e.g. bathing) (Nakimuli-Mpungu, 2012; Nakimuli-Mpungu *et al.* 2013, 2015).

Hazardous alcohol use was assessed using the Alcohol Use Disorders Identification Test (AUDIT). The AUDIT consists of 10 items addressing the frequency, quantity and effect of drinking with a recall period of the previous 1 year. The AUDIT has been used in similar populations in northern Uganda with high internal reliability ($\alpha = 0.91$) (Roberts *et al.* 2011).

Social support was measured using the adapted version of the Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet *et al.* 1988). The MSPSS psychometric properties have been tested in Uganda and found to have good internal consistency and validity in a Ugandan population ($\alpha = 0.83$) (Nakigudde *et al.* 2009).

Perceived stigma was assessed using the Devaluation of Consumer Scale, which estimates the extent to which caregivers believe that people devalue families that include one or more persons who have serious mental illness (Struening *et al.* 2001). The scale has been used in two studies involving caregivers to patients with Schizophrenia and Epilepsy in Uganda (Aganyira, 2013; Ayikoru, 2015).

Number and history of war-related traumatic events was assessed using the traumatic events checklist, a 16-item, locally developed tool which inquires as to whether a participant has a war-related traumatic experience or not (Nakimuli-Mpungu *et al.* 2013).

Child outcomes

Depression was assessed using the 18-item Depression Self-rating Scale (DSRS) (Birleson, 1981). The DSRS has shown good validity and reliability in low-resourced settings (Kohrt *et al.* 2011).

General psychological distress was assessed by the Strengths and Difficulties Questionnaire (SDQ) (Goodman *et al.* 2000). The SDQ has 25 items organized under five scales of five items each, scored on a three-point Likert scale. It has been used in similar settings in Uganda (Okello *et al.* 2007; Kinyanda *et al.* 2013) with a sensitivity of $\geq 60\%$ and adequate specificity in a child/adolescent population in north and east Uganda (Kinyanda *et al.* 2013).

Child perception of parental relationships was assessed with the Inventory of Parent and Peer Attachment (IPPA) (Gullone & Robinson, 2005; Okello *et al.* 2014). Questions were restricted to the participating caregiver and did not include the peer attachment scale. Among school going adolescents in northern Uganda, the Cronbach α for the mother and father sections of the IPPA was 0.85 and 0.88, respectively (Okello *et al.* 2014).

PTSD symptoms were measured with the Revised Child Impact of Event Scale (CRIES-13), which consists of 13 items on intrusion, avoidance and arousal symptoms scored on a four-point scale (Perrin *et al.* 2005).

We used the Adverse Childhood Exposure (ACE) questionnaire (Bruffaerts *et al.* 2010) at study baseline to examine six context-specific intra-familial childhood adversities before the age of 13 years. The Cronbach α for a sample of adolescents living in a similar setting was 0.94 (Okello *et al.* 2013, 2014).

Separation anxiety disorder (SAD), GAD and attention-deficit hyperactivity disorder (ADHD) were measured among children using a diagnostic/categorical tool: the MINI International Neuropsychiatric Interview for Children and Adolescents (M.I.N.I.-KID) (Sheehan *et al.* 2010). It has not been validated for use in Uganda but has been used in similar populations in the country (Okello *et al.* 2007; Kinyanda *et al.* 2013).

Statistical analyses

To estimate the sample size for the study, we assumed a 55% prevalence of mild-to-moderate depression among people in northern Uganda (Ovuga *et al.* 2005) and estimated that the IPT-G intervention would reduce depression in the caregivers by 50% (Bolton *et al.* 2003). With a level of precision of 5% and power of 80%, the sample size for each arm was calculated to be 57 persons. With an expected attrition of up to 15%, the total sample size was estimated to be 132 people, 66 from each arm.

Data were entered using Epidata 3.1 and analysed using Stata statistical software, version 13 (Stata Corp). We explored completeness of data and the missing data mechanism. Study dropout was associated with gender (male caregivers more likely to drop out, $p < 0.01$) and number of children (caregivers with greater number of children more likely to drop out, $p < 0.01$). We therefore assumed that data were missing at random and conducted imputation procedures (10 datasets) using multiple imputation with chained equations (Azur *et al.* 2011). Linear mixed-effects models were estimated for continuous outcomes (SDQ, IPPA, DSRS, CRIES-13, SRQ, AUDIT, functioning, social support, stigma and suicide score) and generalized linear mixed-effects models with a log link and Poisson distribution were estimated for the binary outcomes (SAD, GAD, ADHD, PTSD, major depression and suicide risk) (Zou, 2004). Random effects in all models included participant and village. Fixed effects included treatment group (IPT-G or control), time (baseline or follow-up) and an interaction term of group x time. Additional covariates were included in the model if there was a significant baseline difference between treatment groups, or if the covariate was associated with mean change in the outcome from baseline to follow-up. For the linear mixed-effects models, Cohen's d statistic was calculated as an estimate of effect size by dividing the group x time interaction term by the baseline pooled standard deviation. For the generalized models, relative risk was calculated with associated 95% CIs. All models used $p < 0.05$ as a statistical significance threshold. All participants were included in the intent-to-treat analysis.

Results

Table 2 displays socio-demographic characteristics of the 142 eligible caregivers. Caregivers were predominantly female (76.8%) with an average age of 43; almost all (>98%) were peasant farmers. Caregivers in the TAU arm reported a significantly ($p = 0.04$) higher mean number of traumatic events (8.2) compared with caregivers in the IPT-G arm (6.8). Otherwise, there were no significant differences in the caregiver characteristics. Child participants were 52.8% female with an average age of 14 years, with no significant differences between groups.

Participant retention is summarized in the CONSORT diagram (Fig. 1). Of the 142 participants enrolled, 116 (81.7%) completed a 1-month post-assessment and 121 (85.2%) completed a 6-month post-assessment.

Table 3 displays caregiver outcome scores by treatment arm. Caregiver participants who received IPT-G had a greater reduction in the risk of depression from baseline to 1 and 6 months (both $p < 0.05$) post-intervention compared with caregiver participants who received TAU. Among the other caregiver outcomes, IPT-G participants had a significantly greater reduction in psychological distress at 1 month (SRQ; $p < 0.01$), reported less stigma at 6 months ($p = 0.02$) and increased social support at

Table 2. Baseline characteristics of study sample ($n = 142$ caregiver/child dyads)

	N (%) or mean (s.d.)		χ^2 or <i>t</i> test
	IPT-G ($n = 73$)	TAU control ($n = 69$)	
<i>Caregiver characteristic</i>			
Female	59 (80.8)	50 (72.5)	1.39
Age	43.4 (9.0)	41.8 (12.3)	-0.85
<i>Marital status</i>			
Single/separated/divorced	24 (32.9)	18 (26.1)	1.25
Married/monogamous	33 (45.2)	31 (44.9)	
Married/polygamous	16 (21.9)	20 (29.0)	
Formal education	39 (53.4)	44 (63.8)	1.56
<i>Employment</i>			
Unemployed	0 (0.0)	1 (1.5)	2.15
Peasant farmer	73 (100)	67 (97.1)	
Other employment	0 (0.0)	1 (1.5)	
<i>Religion</i>			
Protestant	9 (12.3)	14 (20.3)	1.77
Catholic	57 (78.1)	50 (72.5)	
Pentecostal	7 (9.6)	5 (7.3)	
Number of children	6.4 (2.2)	6.6 (2.5)	0.46
Number of trauma types	6.8 (3.7)	8.2 (4.2)	2.07*
<i>Child characteristics</i>			
Female	38 (52.1)	37 (53.6)	0.04
Age	14.3 (2.5)	13.6 (2.0)	-1.94
Currently in school	21 (28.8)	23 (33.3)	0.35
Mother alive	71 (97.3)	62 (89.9)	3.28
Father alive	54 (74.0)	54 (78.3)	0.36
Number of adverse events	6.5 (1.9)	6.7 (2.1)	0.71

Means, s.d., *N* and % based on all available data at each time point.

* $p < 0.05$.

6 months ($p < 0.0001$) compared with TAU participants. There were no other significant differences in caregiver outcome change between groups.

Table 4 displays caregiver reported child outcome scores by treatment arm. For the primary outcome of depression, child participants whose caregiver received IPT-G had a significantly greater reduction in depression symptoms at 1 month ($p = 0.01$) and 6 months ($p = 0.03$) compared with children whose caregiver received TAU.

Discussion

For caregivers of children affected by NS, IPT-G delivered by LCHWs working in the government health system, resulted in significant reductions in the risk of depression, psychological distress and stigma, and significant improvement in social support among caregivers compared with those who received TAU. Notably, there

was a significant improvement in their children's mental health, indicated by reduction in depression symptoms, compared with the TAU group.

IPT-G targets depression specifically, and in our study, caregivers who received IPT-G had an 88% reduction in risk for MDD from baseline to the 1-month post-intervention assessment compared with a 46% reduction in risk among TAU caregivers. Treatment effects appeared to be sustained over time: at the 6-month follow-up, IPT-G participants' depression risk remained reduced by 88% from baseline compared with a 57% reduction in risk among controls. These findings are in line with previous studies of IPT-G in South Africa (Petersen *et al.* 2012, 2014). Our study compares favourably with other group PTs in similar settings. In their study among HIV-positive adults in northern Uganda, Nakimuli-Mpungu *et al.* (2015) found no difference in mean depression scores between group support psychotherapy (GSP) and group HIV education (GHE) immediately after intervention, though participants in the GSP group had significantly lower mean depression scores than those in the GHE group 6 months after intervention (Nakimuli-Mpungu *et al.* 2015).

Caregivers who received IPT-G had significantly higher levels of social support at 1 and 6 months post-intervention. Parent-to-parent programmes, as was the case with IPT-G for NS, provide emotional, informational and instrumental support (Tracy & Whittaker, 1987). Consistent with the literature, group psychological interventions result in improved social support among participants and have many potential benefits, including the instillation of hope, acceptance, belonging and altruism (Hogan *et al.* 2002; Petersen *et al.* 2012; Nakimuli-Mpungu *et al.* 2015). Peer support and self-help groups allow members to provide and receive support, and rebuild lasting social networks after a crisis (Tracy & Whittaker, 1987). Interventions that emphasize reciprocal support (e.g. both giving and receiving support) show more encouraging results than those where one only receives support, and more so for diseases considered stigmatizing (Hogan *et al.* 2002). There appears to be a positive relationship between social support and family outcomes including parenting behaviours, parenting attitudes, parent-child interactions and child development (Tracy & Whittaker, 1987).

The significant reduction in perceived stigma levels at 6 months among caregivers who received IPT-G could also be explained by improved social support. As an adaptation to perceived stigmatization, caregivers may withdraw from potential support networks which in turn negatively affects their mental health and coping effectiveness (Perlick *et al.* 2007). IPT-G has been noted to contribute to improved personal agency, resilience and coping (Petersen *et al.* 2012) which could result in decreased levels of perceived stigma and psychological distress.

This study also suggests that PTs delivered to caregivers improve psychological outcomes for their children. Mean depression scores were significantly lower at both time points in children whose caregivers received IPT-G. These findings are consistent with previous research, which showed that reductions in maternal depression mediated improvements in child externalizing and internalizing problem behaviour (Shaw *et al.* 2009).

There were no significant effects of IPT-G on PTSD, GAD, suicide risk, alcohol use and level of functioning among the caregivers. IPT-G is designed specifically to address depressive symptomatology and may require further adaptation than what was conducted in this study to have an effect on PTSD (Campanini *et al.* 2010) or anxiety disorders. Though the scores were higher in the treatment group at 1 and 6 months post-intervention,

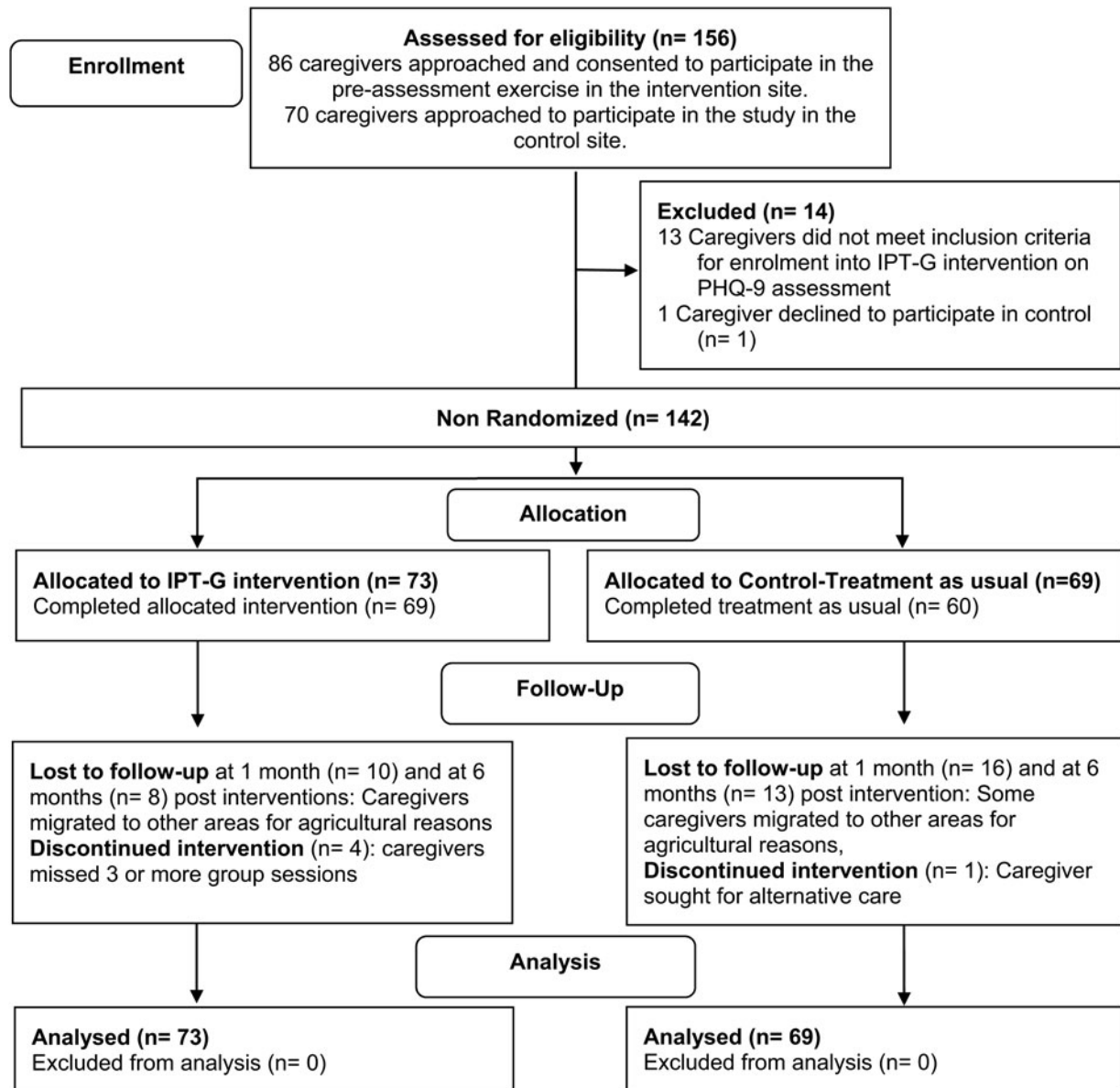


Fig. 1. CONSORT 2010 flow diagram.

there were no significant differences in the level of functioning in the caregivers. This is similar to Nakimuli-Mpungu *et al.*'s finding for a group support (GSP) intervention using a similar measure and conducted in a similar context (Nakimuli-Mpungu *et al.* 2013, 2015). The measure of functioning is based on the performance of activities of daily living and social obligations which have to be met, and hence levels of functioning may not be affected by levels of distress, especially for caregivers who have dependent sick children (Nakimuli-Mpungu, 2012). In our study, there were low rates of alcohol use disorder among caregivers compared with previous findings in similar populations (Roberts *et al.* 2011). Cognizant of the limitations of using interviewer-administered assessments of alcohol use, our results could also be explained by the demands and obligations for families affected by NS (Nakigudde *et al.* 2016). Given the trends in some of the caregiver outcomes, our study could also have been underpowered to detect effects on a number of measures.

This effectiveness study is a model for how PTs can be adapted for government health systems in low-resource settings. It is within the recommendations of Thornicroft *et al.* (2016) who call for community mental health care with service provision by staff in primary care and community settings (Thornicroft *et al.* 2010, 2016). Our findings suggest that community-based interventions for promoting child and adolescent mental health should incorporate strategies to promote caregiver mental health. This study demonstrates that an evidence-based psychotherapy intervention can be delivered effectively and with fidelity by lay counsellors and, critically, that the effects of the intervention on the primary depression outcome were sustained over a 6-month period following the end of the treatment. Lewandowski & others (2016) provide more evidence of sustained effects of IPT-G: positive changes in quality of life and a range of non-mental health outcomes were attributed to the treatment 10 years after the intervention (Lewandowski *et al.* 2016).

Table 3. IPT treatment effects 1 and 6 months after the end of treatment among adult caregiver participants

Outcome (continuous)	Control		Treatment effect	
	Mean (s.d.) ^a	IPT	Cohen's <i>d</i> ^b	<i>p</i> value ^c
SRQ				
Baseline	10.2 (5.2)	10.8 (4.7)	–	–
1 month post-treatment	8.7 (4.6)	4.5 (3.5)	0.80	<0.01
6 months post-treatment	5.9 (5.1)	3.5 (3.4)	0.46	0.06
Alcohol (AUDIT)				
Baseline	1.8 (5.3)	1.6 (4.0)	–	–
1 month post-treatment	2.3 (5.5)	3.0 (6.2)	0.11	0.60
6 months post-treatment	1.3 (3.0)	2.4 (5.4)	0.24	0.29
Stigma				
Baseline	18.3 (3.1)	17.8 (3.8)	–	–
1 month post-treatment	17.6 (3.4)	16.3 (2.5)	0.16	0.56
6 months post-treatment	19.4 (2.7)	16.2 (2.3)	0.65	0.02
Functioning				
Baseline	6.6 (2.4)	7.1 (2.6)	–	–
1 month post-treatment	7.0 (2.3)	8.8 (2.0)	0.44	0.13
6 months post-treatment	8.1 (2.3)	8.8 (1.7)	0.03	0.90
Social support				
Baseline	32.6 (7.9)	33.1 (7.7)	–	–
1 month post-treatment	34.5 (9.5)	38.4 (7.2)	0.36	0.09
6 months post-treatment	33.8 (9.2)	40.4 (6.1)	0.56	<0.0001
Suicide score				
Baseline	4.1 (11.5)	3.9 (9.4)	–	–
1 month post-treatment	2.2 (6.1)	1.3 (4.8)	0.07	0.71
6 months post-treatment	3.1 (8.7)	0.8 (5.5)	0.14	0.32
Outcome (binary)	<i>N</i> (%) ^a		Risk ratio (95% CI) ^d	<i>p</i> value ^c
Depression				
Baseline	30 (43.5)	39 (53.4)	–	–
1 month post-treatment	12 (23.5)	4 (6.4)	0.25 (0.10–0.62)	<0.01
6 months post-treatment	10 (18.5)	4 (6.3)	0.33 (0.11–0.95)	0.04
PTSD				
Baseline	25 (36.2)	23 (31.5)	–	–
1 month post-treatment	28 (52.8)	25 (40.3)	0.88 (0.50–1.56)	0.65
6 months post-treatment	15 (26.8)	20 (30.8)	1.17 (0.51–2.67)	0.72
Anxiety				
Baseline	30 (43.5)	31 (42.5)	–	–
1 month post-treatment	10 (18.9)	17 (27.4)	1.37 (0.79–2.46)	0.25
6 months post-treatment	10 (17.9)	6 (9.2)	0.52 (0.23–1.16)	0.11
Suicide risk				
Baseline	8 (11.6)	12 (16.4)	–	–
1 month post-treatment	4 (7.6)	3 (4.8)	0.42 (0.11–1.53)	0.19
6 months post-treatment	6 (10.7)	2 (3.1)	0.25 (0.06–1.04)	0.06

^aMeans, s.d., *N* and % based on all available data at each time point.

^bCohen's *d* effect size was calculated by dividing the group x time interaction term from the linear mixed-effects model by the pooled s.d.

^c*P* value is the significance level of the group x time interaction term from the linear (or generalized linear) mixed-effects model indicating statistical significance of the difference in change of outcome score (or risk) between the treatment and control groups from baseline to post-assessment. Separate models were estimated comparing change from baseline to 1 month post-treatment and baseline to 6 months post-treatment. Models included fixed effects of group, time and group x time interaction, and random effects of village and individual participant over time. Demographic characteristics that differed significantly between groups at baseline or predicted change in symptom over time were also included in the models as covariates. All models included all participants at each time point following multiple imputation procedures.

^dRisk ratios are the exponentiated form of the group x time interaction term from the generalized linear mixed-effects model with Poisson distribution and log link. This coefficient can be interpreted as a ratio of risk ratios. Specifically, it represents the risk ratio comparing risk at follow-up to risk baseline among IPT-G divided by the risk ratio comparing risk at follow-up to risk at baseline among TAU.

Table 4. IPT treatment effects 1 and 6 months after the end of treatment among child participants

Outcome (continuous)	Control		Between-group treatment effect	
	Mean (s.d.) ^a	IPT	Cohen's <i>d</i> ^b	<i>p</i> value ^c
Depression (DSRS)				
Baseline	15.2 (5.5)	16.9 (5.6)	–	–
1 month post-treatment	14.6 (6.7)	12.9 (4.8)	0.57	0.01
6 months post-treatment	13.5 (7.0)	12.2 (6.5)	0.46	0.03
Strengths and difficulties				
Baseline	15.4 (6.9)	15.6 (5.8)	–	–
1 month post-treatment	15.6 (7.4)	13.8 (7.4)	0.25	0.31
6 months post-treatment	12.0 (5.5)	11.1 (5.4)	0.07	0.74
Attachment				
Baseline	34.2 (8.2)	33.3 (6.0)	–	–
1 month post-treatment	34.0 (10.7)	37.4 (8.0)	0.55	0.05
6 months post-treatment	36.2 (7.3)	37.0 (6.7)	0.22	0.47
CRIES				
Baseline	7.3 (11.2)	8.6 (11.2)	–	–
1 month post-treatment	3.4 (7.5)	3.1 (8.5)	0.18	0.25
6 months post-treatment	2.5 (6.5)	2.4 (7.6)	0.11	0.53
Outcome (binary)	<i>N</i> (%) ^a		Difference in risk ratios (95% CI) ^d	<i>p</i> value ^c
SAD				
Baseline	21 (30.4)	18 (24.7)	–	–
1 month post-treatment	6 (11.3)	8 (12.7)	1.4 (0.35–5.67)	0.63
6 months post-treatment	1 (1.8)	5 (7.7)	5.64 (0.92–34.4)	0.06
GAD				
Baseline	23 (33.3)	15 (20.6)	–	–
1 month post-treatment	15 (28.3)	19 (30.2)	1.17 (0.74–4.15)	0.48
6 months post-treatment	7 (12.5)	4 (6.2)	0.85 (0.31–2.37)	0.76
ADHD				
Baseline	13 (18.8)	17 (23.3)	–	–
1 month post-treatment	10 (18.9)	0 (0.0)	0.09 (0.01–0.76)	0.03
6 months post-treatment	2 (3.6)	2 (3.1)	0.76 (0.11–5.10)	0.78

^aMeans, s.d., *N* and % based on all available data at each time point.

^bCohen's *d* effect size was calculated by dividing the group x time interaction term from the linear mixed-effects model by the pooled s.d.

^c*P* value is the significance level of the group x time interaction term from the linear (or generalized linear) mixed-effects model indicating statistical significance of the difference in change of outcome score (or risk) between the treatment and control groups from baseline to post-assessment. Separate models were estimated comparing change from baseline to 1 month post-treatment and baseline to 6 months post-treatment. Models included fixed effects of group, time and group x time interaction, and random effects of village and individual participant over time. Demographic characteristics that differed significantly between groups at baseline or predicted change in symptom over time were also included in the models as covariates. All models included all participants at each time point following multiple imputation procedures.

^dRisk ratios are the exponentiated form of the group x time interaction term from the generalized linear mixed-effects model with Poisson distribution and log link. This coefficient can be interpreted as a ratio of risk ratios. Specifically, it represents the risk ratio comparing risk at follow-up to risk at baseline among IPT-G divided by the risk ratio comparing risk at follow-up to risk at baseline among TAU.

In comparison to a similar intervention (Petersen *et al.* 2014), the low rate of attrition in our study provides evidence of IPT-G as a feasible and effective PT for moderate-to-severe depression when delivered by trained LCHWs within a task-shifting approach in low-resource settings. Though there are concerns about fidelity and other barriers to effective IPT-G delivery (Lewandowski *et al.* 2016), integration within government health system structures may provide the right platform for sustainable service provision.

Limitations

The trial was non-randomized, thus introducing the potential for bias. Our results indicate that the treatment groups were comparable with respect to baseline values for demographic characteristics and mental health outcomes. That said, lack of randomization increases the likelihood that an unmeasured covariate within the treatment blocks influenced the group differences in outcomes. Because of the context of government roll out of services for

NS, randomization was not possible at the time of our study. Quasi-experimental designs allow the flexibility required to test interventions within community service settings for conditions like NS, which have ethical and socio-political considerations precluding randomization (Stadnick *et al.* 2015).

Although we used some locally developed measures, most of our outcome measures for adults and children have not been validated for the local population. In addition, some of the child assessments were based on caregiver reports and this could have influenced the outcome measures. Parents' perceptions of their child's behaviours and their own functioning may have been influenced by a number of factors such as parenting stress and their expectations of and experiences with services they have received (Stadnick *et al.* 2015). Our study lacks additional informants on children's behaviour and psychological well-being. We are therefore unable to parse changes in caregiver's perception of their children's well-being *v.* changes in child outcomes that could be independently verified by another family or community members. Because many children with NS were not attending school, it was not possible to obtain teacher reports of psychological well-being pre- and post-intervention. We were also not able to enrol more than one child per family to assess the impact on other child family members due to financial and logistical barriers. This should be addressed in future studies. Finally, although the study was adequately powered to observe significant changes in the depression primary outcome, the sample size may have limited our ability to observe statistically significant changes in the secondary outcomes.

In conclusion, this study represents the first application of a PT addressing mental health problems associated with NS, a neuropsychiatric condition with high morbidity and mortality in northern Uganda and South Sudan. Our implementation of IPT-G for NS demonstrates how a PT initially delivered through a highly structured, supervised and well-funded NGO can also be effective when adapted for use in the real-world conditions of low-resourced government health systems. In comparison to TAU, it resulted in significant reduction in the number of adults and children with depression and other mental health outcomes, demonstrating the 'dual' benefits of this intervention. Although results from this study informed the WHO mhGAP pilot in Uganda, a larger randomized study is required to generate further evidence of effectiveness, utility for uptake and scale up of PTs within the public health system.

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Ethical standards. 'The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.'

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