

# CONTROL STUDY

Measuring the impact of IPT-G on adult women with depression in Uganda in Iganga and Mukono Districts, 2019-2020

RESEARCH

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## **A study of interpersonal group therapy (IPT) treatment attribution on decreasing depression severity among depressed women in Iganga District, Makuutu Sub County and Mukono District, Kimenyedde Sub Counties**

Katia Peterson (In Situ Research, LLC, Washington DC), Alec Ulasevich (In Situ Research, LLC) Kari Frame (SMU), Dena Batrice (SMU), Charles Mugoowa (SMU), Leah Tanner (SMU), Rebecca Nabirabwa (SMU), Hope Busingye (SMU), Wilson Mwanja (WHALE)

### **Problem statement**

The Global Burden of Disease Study 2019 listed depressive disorders as the second leading cause of disability worldwide and the study found that Major Depressive Disorder accounted for 4.9% of global DALYs<sup>1</sup>. In Uganda, approximately one in five women experience depression<sup>2</sup>, but most women will never see treatment. According to the WHO, in the African region there are only 1.6 mental health professionals per 100,000 people compared to a global average of 13 per 100,000<sup>3</sup>. Hence, for most people in the African region treatment is nearly impossible to access.

However, not all people will require access to treatment. Several studies report that depression is cyclical and often resolves over time with no treatment. Two studies from developed countries (Belgium and The Netherlands) found that 75% of depressive episodes resolved within 12 months<sup>4-5</sup>. Another two studies from sub-Saharan Africa report that the median length of depressive episodes is one year<sup>6-7</sup>. There is no data from Uganda or neighboring countries on period effects (the effect of time on alleviating depression) versus treatment effects (e.g., medication, therapy.) The lack of data from Uganda has important programmatic implications. In a country where mental health services are not widely available, garnering a better understanding

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<sup>1</sup> GBD 2019 Mental Disorders Collaborators. Global, regional, and national burden of 12 mental disorders in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet Psychiatry*. 2022;9(2):137-150.

<sup>2</sup> Ferrari AJ, Charlson FJ, Norman RE, Patten SB, Freedman G, Murray CJ, et al. (2013). Burden of Depressive Disorders by Country, Sex, Age, and Year: Findings from the Global Burden of Disease Study 2010. *PLoS Medicines*, Nov.

<sup>3</sup> Mental health atlas 2020. Geneva: World Health Organization; 2021.

<sup>4</sup> Bracke, P. (1998). Sex differences in the course of depression: evidence from a longitudinal study of a representative sample of the Belgian population. *Social Psychiatry and Psychiatric Epidemiology*, 33(9), 420-429.

<sup>5</sup> Spijker, J., Graaf, R., V Bijl, R., T F Beckman, A., Ormel, J., & Nolen, W. (2002). Duration of major depressive episodes in the general population: results from The Netherlands Mental Health Survey and Incidence Study (NEMESIS). *The British Journal of Psychiatry: The Journal of Mental Science*, 181, 208-13.

<sup>6</sup> Gureje, O., Uwakwe, R., Oladeji, B., Makanjuola, V. O., & Esan, O. (2010). Depression in adult Nigerians: Results from the Nigerian Survey of Mental Health and Well-being. *Journal of Affective Disorders*, 120(1), 158-164.

<sup>7</sup> Patel, V., Todd, C., Winston, M., Gwanzura, F., Simunyu, E., Acuda, W., & Mann, A. (1998). Outcome of common mental disorders in Harare, Zimbabwe. *The British Journal of Psychiatry: The Journal of Mental Science*, 172, 53-57.

of the natural trajectory of depression over time can help ensure that valuable resources are spent on individuals whose depression may require treatment versus those who can take a “wait and see” approach.

## **Introduction**

StrongMinds Uganda (SMU) is a non-governmental organization founded in 2013 to provide group talk therapy to low-income African women suffering from depression. StrongMinds has been implementing group talk therapy in Uganda since 2014 and has treated more than 350,000 women with depression. StrongMinds model of treatment increases the number of women treated, brings treatment to rural areas that would not otherwise receive therapy, and contributes to growing the body of evidence on group talk therapy’s effectiveness in treating depression at scale in Africa.

StrongMinds’ therapy is based on group interpersonal psychotherapy (IPT), which is a time-bound (12 weeks) and structured talk therapy treatment for major depression and other disorders (including trauma and anxiety). Among StrongMinds’ treatment clients they consistently demonstrate a 15-point average decrease in PHQ-9<sup>8</sup> scores from baseline to endline (12 weeks). In 2014 StrongMinds conducted a small study to compare depression severity between a treatment and a control arm. However, due to limitations in the initial study design and higher rates of attrition than expected, the results of the study were less robust thereby limiting the internal validity and generalizability of the findings to other communities.

## **Study purpose**

The purpose of this study was to measure any differences in depression severity between a control group (no IPT) and treatment group (12-week IPT) over a one-year period (2019-2020).

## **Methods**

Allocation of study-participants was performed at the community level within each sub-county. Participants were recruited from communities that SMU did not currently provide services but had plans to in the future (non-probability sampling). Control and treatment participants were recruited from the same sub-counties but from different communities<sup>9</sup>. This approach to sampling ensured that the populations shared similar socio-demographic characteristics but were sufficiently distanced to minimize spillover effects. Inclusion criteria included: PHQ-9 score greater or equal to ten (depression level = moderate or above), female, aged 18 or older, regularly reside in Makuutuu or Kimenyedde sub-counties. Participants were excluded if they were actively exhibiting or at risk of exhibiting suicidal ideation, diminished mental capacity, and/or unable to understand Lusoga, Luganda, or English.

Participants were recruited by SMU Community Mobilizers (CM). Community Mobilizers are used by SMU to raise awareness about depression and IPT. The CMs arranged small educational sessions on depression for both men and women in each community. After the educational sessions CMs asked women if they would like to be screened for depression. Women were confidentially screened for depression using the PHQ-9. If the woman scored ten or higher on the PHQ-9, the

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<sup>8</sup> The PHQ-9 checklist, developed by Pfizer, consists of nine questions that measure symptoms of depression and frequency over a two-week period. Scores can range between 0 and 27 (a higher score indicates more severe depression). A four-point change is considered clinically significant.

<sup>9</sup> Each sub-county contained two sub-groups: one control community and one treatment community.

CM referred the woman to learn more about IPT. For the control population, the CM provided general information about future SMU programs<sup>10</sup>. The CM made clear that eligibility for IPT was not contingent on participating in the study. If the woman was interested in learning more about the study, she was referred to a data collector for more information about the study and consent to participate.

Allocation of study participants proceeded in two steps. Five-hundred total clients were sampled, with 250 from each sub-county. Within each sub-county, 125 were allocated to treatment and 125 to control sub-groups<sup>11</sup>. Study tools included the PHQ-9 and a survey of well-being. Indicators of well-being included: experiences of pain, employment, food intake, protected shelter, school attendance among household children, and social support. All tools were translated into Lusoga, Luganda, and English. Data was collected in person by an independent data collection firm (WHALE) at baseline (PHQ-9 scores + well-being indicators), 6-months (PHQ-9 scores only), and endline (12-months) (PHQ-9 scores + well-being indicators).

Repeated measures analysis of variance (Generalized Linear Model in SPSS) was used to analyze PHQ-9 scores. The analysis compared the effects of time of observation (baseline, 6 months and 12 months) in relationship to treatment condition (or no treatment condition). A Chi-Square test was used to analyze change in measures of well-being between baseline and endline for all indicators except for overall health (ANOVA).

## **Results**

The final sample size was 186 and 185 participants in the treatment and control group respectively. Due to attrition, the sample size was too small to compare sub-groups by sub-county so the data was pooled for the analysis. Only the participants with valid scores for all three time periods were included in the analysis.

A separate sub-group analysis was conducted to determine if those lost to follow-up were different from the population. No significant difference was found in regard to demographics, PHQ-9 scores, or measures of well-being.

### *PHQ-9 scores*

The analysis revealed a highly significant main effect for time of observation and treatment condition. PHQ-9 scores decreased for both cohorts at 6 and 12 months. However, a significant time of observation by treatment condition interaction indicates that the magnitude of difference between PHQ-9 scores for treatment and control groups was contingent on the time of observation ( $F=40.864, p<0.001$ ). The greatest difference in depression severity was at the 6-month time point but that difference decreased at 12 months.

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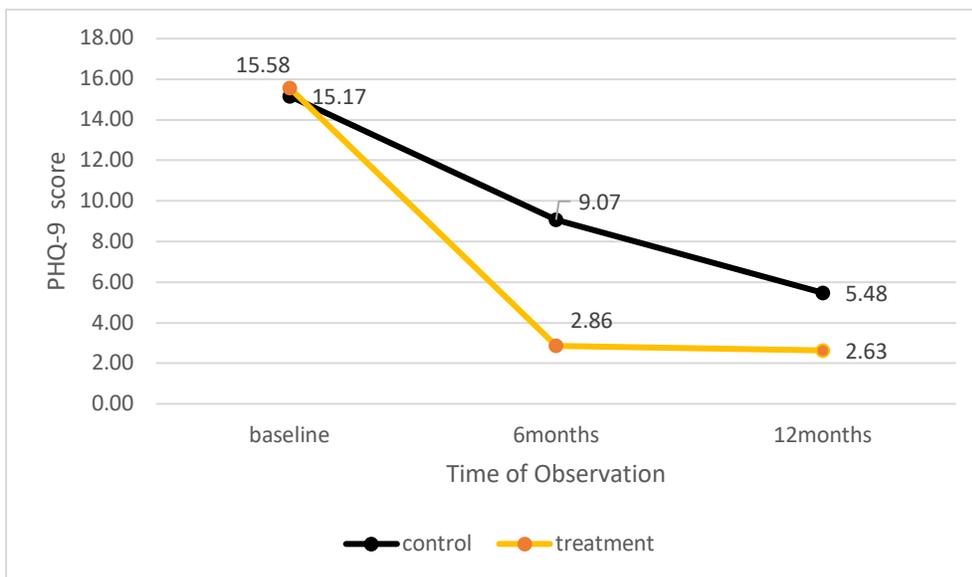
<sup>10</sup> Mobilizers only provided basic information about SMU in order to minimize response bias. CMs informed the community that within the next 12-18 months SMU will be establishing a community presence but they did not provide any detailed information about IPT unless specifically asked.

<sup>11</sup> The sample size is calculated at 100 subjects in each sub-group. The calculation is derived from previous analysis results of StrongMinds' time series data. The study is powered at 80%,  $\alpha = 0.05$ ,  $SD= 4$ , and effect size=2. An additional 25 participants were sampled to account for attrition.

- Average PHQ-9 scores for the treatment and control sub-groups were similar at baseline (15.17 vs. 15.58,  $t=1.15$ , n.s.).
- The average PHQ-9 score at 6 months was lower for both groups in comparison to baseline, but the average score for the treatment group was significantly lower than for the control group (2.86 vs. 9.07,  $t=13.8$ ,  $p<0.001$ ).
- The average PHQ-9 score for the treatment group at 12 months was similar to the average PHQ-9 score at 6 months (2.86 vs. 2.63).
- Although average PHQ-9 score for the control group declined at 12 months, the mean PHQ-9 score for the treatment group was still significantly lower than the control group (2.63 vs. 5.57,  $t=6.45$ ,  $p <0.001$ )<sup>12</sup>.

Another metric commonly used by StrongMinds is the percentage of patients who, at the end of therapy, have minimal levels of depression (<5 points on the PHQ-9). At 12 months follow-up, 79% of treatment participants had minimal levels of depression compared to 49% in the control group ( $p<0.001$ ).

**Figure 1: Treatment by Time of observation interaction**



### *Measures of well-being*

Measures of wellbeing were included to 1) measure the impact that depression treatment has on these indicators and 2) better understand which measures of wellbeing should be routinely measured within the programs. A Chi-Square test was used to measure differences between the treatment and control groups. Two categories were created for comparison. The first category were

<sup>12</sup> Bonferroni correction was used to account for multiple comparisons.

participants who reported no difference or worsened in their status/symptom between baseline and endline, and the second category are those who reported improvement in their status/symptom.

There were no statistically significant changes in employment status and access to protected shelter between baseline and endline in either the treatment or control cohorts. Due to high levels of school attendance among children in both cohorts at baseline it was not possible to analyze changes between baseline and endline.

1. Overall health (*How would you rate your overall health?*)

Respondents rate their health from 1-5<sup>13</sup>. An average score was calculated at baseline and 12 months. A repeated measures ANOVA (time: baseline vs. endline within treatment group: treatment vs. control between groups) was used to analyze the differences in reported health between treatment and control groups. Overall, participants reported better health at baseline than at 12 months (3.09 vs. 2.63) (F=66.13, p<0.001) regardless of the treatment condition (i.e., main effect of time of observation). However, when looking at the interaction effect, even though the quality of health was similar between the treatment and control groups at baseline, at endline the treatment group reported statistically significantly lower quality of health than the control group (2.34 vs. 2.91) (F=9.16, p=0.003). Even though the difference is statistically significant it is unlikely the difference is clinically meaningful.

2. Reported pain (*Have you experienced consistent body or head pain for more than three days in the last 7 days?*)

Comparison of the treatment and control groups showed no statistically significant differences between the groups regarding those who reported an improvement in pain between baseline and endline (34% vs 35% respectively) (Chi-Square 0.22, p=0.88).

Body pain		
	No change or got worse	Improvement
Control	65.40%	34.60%
Treatment	66.10%	33.90%

3. Food security (*During the last 24 hours how many meals did you and other household members have?*)

Comparison of the treatment and control groups showed a statistically significant difference between the groups regarding those who reported an improvement in their food security. Among

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<sup>13</sup> The mean of reported health was averaged to produce results for this indicator. Health was reported as an ordinal value: 5=very good, 4=good, 3=neither good nor bad, 2=poor, 1=very poor.

the control group, only 14% reported an improvement in their food security between baseline and endline compared to 39% in the treatment group (Chi-Square 31.60,  $p < 0.001$ ).

Food security		
	No change or got worse	Improvement
Control	86.50%	13.50%
Treatment	60.80%	39.20%

4. Social support (*Do you have someone in your life to turn to for suggestions about how to deal with a personal problem?*)

Comparison of the treatment and control groups demonstrated no statistically significant difference between the groups regarding those who reported gaining a confidant between baseline and endline (27% vs 24% respectively) (Chi-Square 0.47,  $p = 0.49$ ).

Social Support		
	No change or got worse	Improvement
Control	76.20%	23.80%
Treatment	73.10%	26.90%

StrongMinds IPT is based on the premise of building strong social support systems so that after therapy people can rely on these networks for support. Women in the control group were not part of a therapeutic group and it is not clear why there is an increase in the percentage of study participants who report a confidant at endline. One hypothesis is that in 2018 and 2019 the Ugandan government implemented a number of "operation wealth creation" activities that may have required beneficiaries to form self-help groups (e.g. savings and credit groups) which led to new friendships. Another possibility is that the survey question about having a confidant itself prompted some behavior change.

### Limitations

The study faced two important limitations. First, only participants who had data at all three sampling time points were included in the analysis. Outside of the study protocol, an endpoint analysis was conducted to utilize all measurement occasions for non-completers. The results were not significantly different from the completer analysis. The purpose of the study was to assess the full efficacy of treatment, under optimal circumstances, compared to no treatment in order to understand period effects on depression severity (per protocol design). A shortcoming of this approach is that participants lost to follow up may be sufficiently different in characteristics to bias the results. However, the percentage lost to follow up was similar in both cohorts. Secondly, environmental factors play an important role on a person's well-being. The study locations are primarily agrarian and rely on rains to ensure a good harvest. Additionally, these areas are impoverished so any small economic improvement may have an outsized role on well-

being independent of a mental health intervention. Lastly, in future studies, we would include an additional follow up measurement occasion for the control arm at 12 weeks post-baseline. This would be included to compare the immediate effects of therapy in the treatment group to the relatively short time between baseline and 12 weeks in the control arm.

## **Conclusions**

The study indicates that depression severity among control arm participants did decrease over the one-year time period in the absence of treatment (period effects). However, the treatment effect is much more pronounced especially at the six-month time point. Although the average PHQ-9 score among control participants is nearly 10 points lower than at baseline, the average score is still twice that of the treatment group (2.63 vs. 5.48). The results from the analysis of well-being indicators are less conclusive although not less intriguing. The results raise important programmatic questions such as what other factors can positively impact well-being other than treatment? How can mental health practitioners, and other organizations that seek to improve overall well-being of communities, leverage those factors – perhaps in combined or sequenced service delivery? Feedback from the field suggests that repeated exposure to questions regarding wellbeing and social support could be catalytic in an individual’s awareness of wellbeing deficits in their life and subsequently impact their health- and wellbeing-seeking behaviors. There may also be an element of reporting bias by subjects at baseline that are no longer present at follow-up amongst the treatment participants. The trust, bonding, and social support built in therapy could positively influence an individual’s comfort in truthfully disclosing indicators of productivity, social support, food security, and child wellbeing, whereas the control participants may not have achieved similar levels of comfort in the absence of therapy. The study also highlights the need to question the validity of certain metrics of well-being that are used in other countries but may not be as applicable in the Ugandan context. StrongMinds will use this opportunity to develop and test new metrics in order to more accurately and robustly capture treatment effects.