

Group-Based Cognitive Behavioral Therapy (CBT) Training Improves Mental Health of SME Entrepreneurs

Experimental Evidence from Conflict-Affected Areas of Pakistan

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Abstract

Mental health, well-being, and lasting economic outcomes are intimately connected. However, in geographies marked by fragility, conflict, and violence (FCV), entrepreneurs of small and medium size enterprises (SMEs) experience chronic stress and poor mental health on a regular basis. These issues can hamper performance and quality of life for the entrepreneurs, and can dampen the benefits of existing financial and business assistance programs. Few proven rigorous interventions are known. This study tests the hypothesis that a five-week group Cognitive Behavioral Therapy (CBT) training called Problem Management Plus for Entrepreneurs (PM+E), in combination with financial assistance, could be more effective at reducing psychological stressors of SME entrepreneurs in FCV contexts than financial assistance alone. Meaningful and statistically significant improvements in mental health were achieved, with improvements persisting and increasing beyond the

immediate post-intervention period. Based on analysis of pooled data across two follow-up rounds (at five weeks and three months post-intervention), entrepreneurs in the treatment group experienced statistically significant reduction in the intensity and prevalence of depression and anxiety symptoms (measured by the Patient Health Questionnaire Anxiety and Depression Scale) and higher levels of well-being (measured by the World Health Organization Well-Being Index) compared with the control group. The effect was marked for those experiencing mild/moderate levels of depression and anxiety, suggesting the clinical value of such low touch interventions. Overall, the study demonstrates that empirical research through Randomized Control Trials (RCTs) can be conducted in challenging, FCV settings through appropriate rapid training of local researchers and non-specialist providers (NSPs) at a low cost, yielding scalable programmatic and policy level lessons.

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Group-Based Cognitive Behavioral Therapy (CBT) Training Improves
Mental Health of SME Entrepreneurs:
Experimental Evidence from Conflict-Affected Areas of Pakistan¹

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Keywords: randomized field experiments, entrepreneurship, fragility, conflict, violence, uncertainty, mental health, depression, anxiety, well-being, stress, cognitive behavioral therapy, human capital, small medium enterprises, risk, behavioral economics.

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1. Introduction

The increase in conflict and natural disasters around the world has affected nearly 132 million globally, with conflict continuing to be the main driver of growing humanitarian needs (UNOCHA 2019). The pattern of fragility, conflict, and violence (FCV) engulfing many parts of the world today is associated with long-term psychological consequences (Murthy and Lakshminarayana 2006). Parts of the Khyber Pakhtunkhwa (KPK) province and the Federally Administered Tribal Areas (FATA) of Pakistan have suffered from such armed conflict for the last 3 decades. The 2009-10 insurgency and subsequent security operations displaced an estimated 2 million people from both regions. Severe damage to infrastructure and livelihoods has negatively impacted the social and economic fabric of the entire region, which now ranks among the poorest in the country.

Epidemiological studies from these areas in Pakistan have shown high rates of common mental disorders (such as depression and anxiety) among the general population. A meta-analysis of a subset of relatively rigorous post-conflict surveys showed the prevalence of depressive symptoms to be around 17.3 percent (Steel and others 2009).² Global estimates of productivity losses due to depression are estimated to be around US\$1 trillion dollars per year globally (World Health Organization (WHO) 2017). In this context, the question of the impact of common mental disorders, such as depression and anxiety, on economic productivity in FCV regions is a critical one (British Psychological Society 2011).³ Since economic activity in FCV regions is heavily dominated by small and medium enterprises (SMEs) whose owners are prone to high levels of stress (Ang, 1991), it is pivotal to understand better the extent of prevalence of mental health challenges among SME entrepreneurs as well as its impact on their health and economic outcomes.

Mental health, well-being, and lasting economic outcomes are intimately related. The WHO defines mental health as “a state of well-being in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community” (WHO 2014). There are several arguments to be considered for why researchers interested in improving economic outcomes in a broader sense need to focus on the mental health and well-being of SME entrepreneurs, rather than focusing on productivity alone. First, well-being is a multi-dimensional construct that is a robust predictor of health, productivity, and retention outcomes at the firm-level (Sears and others 2013). Second, depression in parents is associated with children’s poorer physical health, lower human capital attainment, and the onset of psycho-pathology later in life, leading to multi-generational suboptimal health and economic outcomes (National Research Council (US) and Institute of Medicine (US) Committee on Depression, Parenting Practices, and the Healthy Development of Children 2009). Finally, from a social justice point of view, freedom to achieve well-being is of primary moral importance, and is to be understood in terms of people’s

² The unadjusted weighted prevalence rate of depression across all studies was found to be 30.6 percent. A more conservative estimate, based on 26 surveys that combined diagnostic interviews with representative samples, found the prevalence across the studies to be 17.3 percent.

³ Common mental disorders are defined as depression, generalized anxiety disorder (GAD), panic disorder, social anxiety disorder, phobias, obsessive-compulsive disorder (OCD), and post-traumatic stress disorder (PTSD).

capabilities, that is, opportunities *to do and be what they have reason to value* (Sen 2000). Lack of mental health affects this freedom as well as the ability to lead a productive and healthy life.

Despite this, there is very little research about interventions that could address the poor mental health among small business owners in rebuilding the economy of conflict-affected regions. Most interventions for SME entrepreneurs restrict themselves to improving sales or profits at the firm level (which are important for growth and job creation), but tend not to look more deeply at questions of quality of life, human capital, and related inter-generational effects of SME entrepreneurs. Towards filling some of the gaps in this area of work, the aims of this study are threefold: 1) to develop a research toolkit to enable rapid and safe collection of data from conflict-affected settings to inform intervention development; 2) to develop a feasible and culturally appropriate psychosocial training intervention to improve mental health and well-being outcomes of SME entrepreneurs; and 3) to evaluate the feasibility and impact of implementing the intervention in this population.

As peace has returned to the region, the 2012 World Bank-supported Economic Revitalization of KPK and FATA Project (ERKF) is working toward the rehabilitation of SMEs and the creation/restoration of jobs. This support is in the form of financial cash transfers, or grants, provided to individuals who then use the funds to re-establish businesses affected by conflict in their locality. The envisioned mental health and well-being intervention, which aims to improve psychosocial and business outcomes of SME entrepreneurs, was built on the ERKF program in KPK.

The key questions explored in this study are:

- What is the incidence of mental health conditions among SME entrepreneurs in low-capacity or FCV contexts? Is it a problem - why focus on it?
- Are there existing psychosocial interventions that can be leveraged to improve mental health among SME entrepreneurs in FCV contexts? How can these interventions be adapted to the local/ KPK context?
- To what extent is the chosen psychosocial intervention effective in improving mental health and well-being of SME entrepreneurs in the KPK region, when combined with cash grants (compared to cash grants only)?
- To what extent does the chosen psychosocial intervention improve business outcomes?

The first two questions are addressed through the literature review and a qualitative analysis conducted at the baseline. The midline evaluation of the intervention is used to answer the third question. As it is associated with business performance outcomes, the fourth question requires a longer period to be properly addressed. *This paper, therefore, focuses on the first three questions, with the fourth being the subject of a longer-term endline assessment to be completed 18 months post-intervention.*

This paper documents the incremental effects of a five-week group Cognitive Behavioral Therapy (CBT) based training intervention - over and above the effect of receiving cash grants - on reducing depression and anxiety, as well as improving well-being among SME entrepreneurs in conflict-affected parts of Pakistan. Entrepreneurs in the treatment group received the

intervention as well as cash grants, whereas those in the control group received only cash grants. The study, conducted with 235 SME entrepreneurs, found that CBT leads to improvements in mental health outcomes in the short run. Meaningful and statistically significant improvements in mental health were achieved, with improvements persisting and increasing beyond the immediate post-intervention period. Three months after the intervention, based on analysis of pooled data across two follow-up rounds (at five weeks and three months post-intervention), entrepreneurs in the treatment group experienced statistically significant reduction in the intensity and prevalence of depression and anxiety symptoms (measured by the Patient Health Questionnaire Anxiety and Depression Scale) and higher levels of well-being (measured by the WHO-5 Well-Being Index) compared with the control group. The effect was marked for those experiencing mild/moderate levels of depression and anxiety, indicating the clinical value of such low touch early interventions. Overall, the study demonstrates that empirical research through Randomized Control Trials (RCTs) can be conducted in challenging, FCV settings through appropriate rapid training of local researchers and non-specialist providers (NSPs) at a low cost, yielding scalable programmatic and policy level lessons.

2. Why Focus on the Mental Health and Well-Being of SME Entrepreneurs?

2.1 Global Literature Review

It is widely recognized that SMEs are a lifeline for job creation and economic growth in developing countries, including those affected by fragility, conflict, and violence (FCV). However, SME entrepreneurs deal with unusually high levels of uncertainty and experience cognitive resource depletion, which have high psychological and physical health costs (Fernet and others 2016; Monsell 2003). Studies show that individuals with a leadership predisposition and independent work arrangements, including entrepreneurs, tend to be more vulnerable to stress, alienation, loneliness, emotional turmoil, and burnout (Rokach 2014; Akisal and others 2005). Given the comorbidity of stress prevalence with physical and mental health conditions, the risk of rising health care costs due to job stress for entrepreneurs can be significant (Buttner 1992; Jamal 1997; Jamal and Badawi 1995; Lewin-Epstein and Yuchtman-Yaar 1991).

Compared to large enterprises, SME entrepreneurs are at a greater risk for depression, anxiety, and other mental health conditions (Akande 1994; Ang 1991; Boyd and Gumpert 1983; Cocker, Martin, Scott, Venn, and Sanderson 2013). SME entrepreneurs lacking diversified capital, stable sources of income, or delegation opportunities tend to suffer from more stress and anxiety compared with their peers in salaried jobs or those working in larger firms. The high cognitive burden experienced by SME entrepreneurs can lead to weakened psychological health that can hinder their capacity to decide and act, thereby increasing counter-productive work behaviors. This can result in lower sales turnover over the long run (Akande 1994; Dewe and Guest 1990; Harris and others 1999).

In FCV contexts, the combination of regular business-related entrepreneurial stressors with the uncertainties in the external environment can amplify poorer psychological outcomes and hamper business performance (Saraf and others 2018). The high levels of unpredictability,

perceived risk, and cognitive depletion among entrepreneurs in such contexts can, in turn, lead to poor psycho-emotional and psycho-pathological outcomes (Ahmad and Salim 2009; Grant and Ferris 2017; Rockmore 2016; Tahir 2016).

The literature points to three mechanisms by which stress can affect the business performance of SME entrepreneurs, namely: (i) the depletion of psychological resources, which lowers performance by reducing their capacity to cope with work-related stress, as well as their ability to perform complex tasks (Fernet and others 2016; Harms and others 2017; McGuire and Botvinick 2010; Meglino 1977; Spears 2011; Vohs and others 2008); (ii) erosion of their influencing and motivating role within the organization due to anxiety and depression, which leads to a negative mood contagion effect on employees, including communication barriers, an increase in conflict and absenteeism, and lower team performance (Brummelhuis and others 2014; Harms and others 2017; Johnson 2008; Sy, Côté, and Saavedra 2005); and (iii) counterproductive work behavior as a result of reduced self-regulation capacity and weakened cognitive controls (Boye and Jones 1997; Tucker and others 2009). All these result in lower productivity, which is defined as lost value for the enterprise, typically defined as being away from work (for example, short-term absenteeism), or not being fully productive in meeting expectations while at work (defined as presenteeism) (Sears and others 2013).

Even though there are several programs targeting SME growth and entrepreneurship policy in FCV contexts, most of these do not focus on improving the psychological well-being of entrepreneurs, which could be a path to improved productivity through the expansion of their capability to function (Sen 2000). To the best of our knowledge, almost no empirical work exists in the domain of understanding what would enable a sense of greater well-being among SME entrepreneurs, and whether enhanced well-being is linked to better business outcomes. These are some of the gaps the study aims to fill.

Despite the strong empirical evidence regarding the poor mental health status of SME entrepreneurs, market failures and constraints in FCV-affected countries prevent appropriate support services from reaching them. These constraints are well-acknowledged in the economic, public health, and anthropology literature: information asymmetries in the health system that collect information only from in-coming patients, a crippling shortage of trained health providers, cultural norms that regard adult breadwinners (especially men) as invincible, to name a few.

The training intervention was not aimed at resolving the market failures mentioned above but it helped to test two mechanisms that contribute to alleviating them. On the supply side, the pilot tested whether rapidly trained non-specialist providers (NSPs) could help in executing psychosocial well-being interventions effectively. On the demand side, it gathered evidence on the type of framing and messaging which would help navigate the cultural norms and increase demand for such services. These results would inform policy decisions on how to scale approaches that were piloted in addition to undertaking a systematic reform of the health system. These reforms are, however, outside of the scope of discussion of this paper.

2.2 Rapid Needs Assessment of Stressors in Pakistan's KPK Province

To seek a deeper understanding of the contextual factors and training needs of SME entrepreneurs working in Pakistan's KPK areas, a needs assessment was conducted using a semi-structured interview guide that explored the nature of the problems entrepreneurs face, perceived causes and their effects, as well as current practices in dealing with the impact of these challenges. This was piloted among a small sample of 17 SME entrepreneurs who were ERKF grantees (see Annex 1 for details on the rapid needs assessment sample).

The Assessment confirmed that the chronic adversities prevailing in KPK manifest themselves in the form of 'distress' for SME entrepreneurs (for example, inability to concentrate on work, poor sleep and appetite, low self-esteem, anxiety about future of their businesses, etc.) (Saraf, Rahman, Hamdani, Jamison, and others, 2018). Participants linked these feelings of distress to low mood and low energy, impaired quality of life, poor self-esteem, and increased conflicts within the household. Distress also caused feelings of negativity, hopelessness, and agitation — leading to suicidal thoughts in some cases. In the long-term, these were linked with the inability to problem solve and innovate, low quality of work, and low return on investments. All of these, collectively, were impacting their sense of well-being and their productivity.

The Assessment also identified the potential utility of a psychological intervention program to improve the resilience, productivity, and personal efficacy of SME entrepreneurs. It highlighted the need to deliver training in the local language (Urdu), form groups based on 'affinity' (that is, key characteristics such as gender, education, and business type), and hold sessions in a central location that is accessible, acceptable, and safe for both male and female entrepreneurs. These provided useful guidance in the design of the intervention. More details about the rapid needs assessment and its findings are found in Chapter 2 of the main report (Saraf, 2019).

BOX 1: Rapid needs assessment results: Major causes of perceived stress among SME entrepreneurs in the KPK region of Pakistan

Findings show unacknowledged mental well-being issues experienced by SME entrepreneurs and their common causes. The following issues emerged as major causes of perceived stress:

- i. **Safety and security concerns:** Due to frequent violence, people report being in constant fear for their safety and the safety of their loved ones. Their activities are strictly monitored through ongoing surveillance by law enforcement agencies. This restricts business activities by limiting the movement of international business delegates in the region, as well as by impeding the promotional, sales, and capacity-building activities of businesses.
- ii. **Financial difficulties:** Since most businesses were either destroyed or experienced significant drops in sales due to the security crisis, financial difficulties were reportedly widespread. Most entrepreneurs say that they lack the financial resources to reestablish and sustain their businesses. As such, they have resorted to loans, which become difficult to repay due to unfavorable economic conditions for businesses, including inflation (which lowers sales).
- iii. **Lack of appropriate skills:** Entrepreneurs perceive that they lack the appropriate technical and soft skills to run their businesses, and view such deficiencies as barriers to achieving higher productivity and product

quality. The low quality leads to low returns on investments, and decreased profitability and earnings for everyone — lowering enthusiasm in consequence.

iv. Disturbance in family life: Entrepreneurs report that the uncertainties lead to distress and frequent disagreements in their personal, professional, and family lives. The unstable socio-political environment, financial constraints, and long working hours are perceived to disturb their work-life balance. This, in turn, impairs their family and social lives, and for some, the lack of family support can make this situation worse.

v. Gender-specific issues for female entrepreneurs: Pervasive social and cultural barriers, lack of technical skills, limited availability of capacity building opportunities, household responsibilities, and lack of financial and emotional support from families were reported as additional barriers for female entrepreneurs.

Source: World Bank Group, 2018; Saraf, Rahman, Hamdani, Jamison, and others, 2018

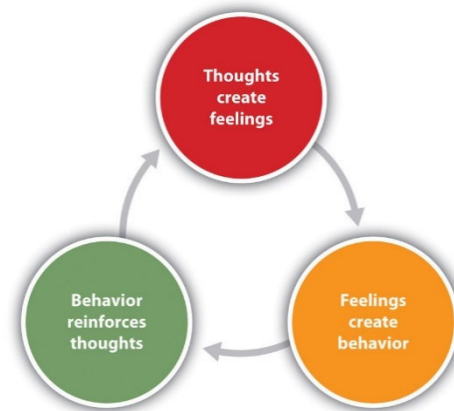
3. Psychosocial Training Interventions

3.1 Literature on Relevant Interventions

Behavioral economics and cognitive psychology provide a set of tested tools to address stress and cognitive resource depletion, including restoration of emotional well-being in the workplace. One key approach found across psychological interventions is CBT. It has been commonly used in psychological settings, and more recently, in economic interventions with youth and adults in FCVs. Greater exploration of this approach in the context of mental health improvements for SME entrepreneurs in FCV situations is documented in the following paragraphs.

The simple idea behind CBT (Figure 1) is that an individual's unique patterns of thinking (cognition) and feeling are significant factors in how they experience their surroundings and the type of actions they take (behavior), both desirable and undesirable. As these patterns have such a significant impact on performance, it follows that addressing these patterns — where they have become maladaptive due to mitigating circumstances — can change their experience of the world and hence, actions and performance (Martin 2016). CBT workshops can help to generate a more positive outlook, developing resilience and improving decision-making abilities and will-power. CBT tends to be short (3-4 months) and inexpensive (US\$300-\$750 per participant). It can include somatic interventions, such as deep breathing exercises. In some cases, CBT has been delivered by NSPs with positive results.

Figure 1: Cognitive Behavioral Therapy Framework



Source: Cognitive Behavioral Therapy LA (<http://cogbtherapy.com/about-cbt/>)

Traditionally, CBT has been used in the context of mental health and has been shown to successfully reduce depression across various clinical demographic groups (Craigie and Nathan 2009; Fava and others 2004; Kessler and others 2009; Mataix and others 2015; Mohr and others 2005; Spector and others 2014; Rahman and others 2019). Evidence of successful CBT applications and similar psychosocial interventions is now growing to include non-mental health areas as well. One of the most effective applications of CBT is the “Becoming a Man” (BAM) program, which succeeded in significantly reducing violent crime arrests and improving both school engagement and graduation rates among at-risk adolescents in Chicago. The changes can be attributed to slowing down the thought process of individuals to allow for “slow”, deliberative reflection to override “fast”, automatic decision-making (Heller and others 2013, 2015).

A similar study in Liberia used a CBT module designed to foster self-regulation, patience, and a non-criminal identity and lifestyle for at-risk youth. It succeeded in dramatically decreasing crime and violence (especially when followed by a cash grant) (Blattman and others 2017). A study in the Netherlands, conducted with self-employed individuals, used two types of CBT. One was delivered by psychotherapists and the other was provided by labor experts. The goal was to successfully reduce the number of sick days taken due to psychological complaints (for example, anxiety, depression, burnout), and improve psychological outcomes (Blonk and others 2006).

More recently, a number of trials have been conducted using the CBT-informed Problem Management Plus (PM+) module. This intervention tends to be brief, group-based, and can be delivered by NSPs. One such study in rural SWAT, Pakistan, used a group-based CBT module to achieve clinically significant reductions in depression and anxiety among women with common mental disorders (Rahman and others 2019).

Some non-CBT approaches have proven effective to improve business outcomes. In an action-regulation training experiment, focusing on self-regulation and active behavior in entrepreneurship improved personal initiative behavior and led to increases in sales (27 percent) and the number of employees (35 percent) (Frese and others 2016). Following a similar approach,

a recent study in Togo used a psychology-based, personal initiative training, which taught proactive mindset and focused on entrepreneurial behaviors. It led to an increase in firm profits by 30 percent (compared to an 11 percent increase with traditional business training) (Campos and others 2017). In both studies, however, there was no baseline verification to assess whether the participants were experiencing mental health challenges, and whether the training improved mental health and well-being outcomes.

A summary of the core themes, structure, and delivery of each curriculum is provided in Annex 2. However, the literature is relatively scant when it comes to rigorous impact evaluations of CBT-based approaches for entrepreneurs, which represents an area of opportunity for this study.

3.2 Development of PM+E (Problem Management Plus for Entrepreneurs) Curriculum for KPK Entrepreneurs

Among the several available CBT curricula, the Problem Management Plus (PM+) curricula was chosen and adapted for this intervention for three reasons.⁴ First, its focus on managing stress, problem management, behavioral activation, and strengthening social support was found to be relevant to the issues faced by entrepreneurs as revealed by the rapid needs assessment. Second, the literature showed that it has already been tested in KPK for contextual validity, albeit for different clinical beneficiary groups. This ensured that the language of the standard curriculum was appropriately tested for this local context, and that it could be further built on. Finally, compared to some other curricula, it could be delivered by trained NSPs. This would be a critical factor for implementation in conflict-affected areas that report a crippling shortage of technical staff. All these factors would allow for the intervention to be implemented on time, at a low-cost, and at the appropriate scale.

Once the core PM+ curriculum was identified, the framing of the curriculum was adapted to make it feasible to implement among SME entrepreneurs who tend to be high-achievers and are suffering from an *unrecognized* burden of mental health problems but not clinically diagnosed yet. The revised curriculum was called PM+E (Problem Management Plus for Entrepreneurs).⁵ The curriculum was contextualized in leadership and adaptive skills and focused on self-improvement for well-being and business outcomes rather than use the traditional language found in the PM+ curriculum. Such framing helped to improve the acceptability of the training program among SME entrepreneurs and circumvent the cultural reservations around “mental health”. For example, distress-generating scenarios and anonymized real-life case studies - pertinent to the business community - were included in the curriculum with lessons on stress management, problem solving, behavioral activation, strengthening social networks, and self-care. In doing so, rather than targeting specific treatments for clinical individuals, the

⁴ Permission obtained from WHO for use of the Urdu curriculum and its adaptation. (Source: https://www.who.int/mental_health/emergencies/problem_management_plus/en/)

⁵ Henceforth, PM+ and PM+E will be used interchangeably throughout the report.

intervention focused on adaptive skills for at-risk non-clinical populations, which increased its acceptability among SME entrepreneurs.

The PM+E intervention was designed to provide the entrepreneurs with a skillset that could be applied to stressful situations in their everyday life and work to help them to negotiate such challenges in an adaptive fashion. The core content of the 5-week training intervention is summarized below.

1. **Stress management:** The stress management strategy improves the management of stress related to business and personal problems and helps participants to remain calm during moments of stress. This includes somatic and deep breathing exercises.
2. **Problem solving:** This is a strategy to apply in situations where a participant is experiencing practical problems (for example, loss in business, conflict in the family, and so on). It gives participants real-time tools to deal with daily problems, such as breaking down a complex problem into what is within their control and what is outside, and strategies to respond to both categories.
3. **Behavioral activation:** This strategy is aimed at improving participants' levels of activity (relevant particularly where regular activity has been affected due to stressful conditions). In addition, it introduces participants to an "experimental mind-set" to encourage them to break out of the vicious cycle of the problems/adversity by trying out different ways of managing the challenges of everyday life.
4. **Strengthening support network:** Individuals with distress can isolate themselves from supportive people and organizations. The module focuses on strategies for strengthening a participant's social support network (for example, with trusted friends, family members, co-workers, or community organizations) that can promote well-being.
5. **Self-care:** This strategy is centered around principles of peace and calmness that participants can use to take better care of themselves and improve their physical and mental health.

The training is brief, consisting of five days of face-to-face training spread over five weeks, followed by Whatsapp reminder messages. A 'cascade' model of training and supervision was used that involves the training of local coaches in the curriculum by master trainers. The cascade model of training and supervision was tailored to address the lack of specialists, as well as mobility restrictions and security concerns of delivery agents and participants in such settings. More details about the training the trainer module and quality control mechanisms can be found in Chapter 3 of the main report (Saraf, 2019).

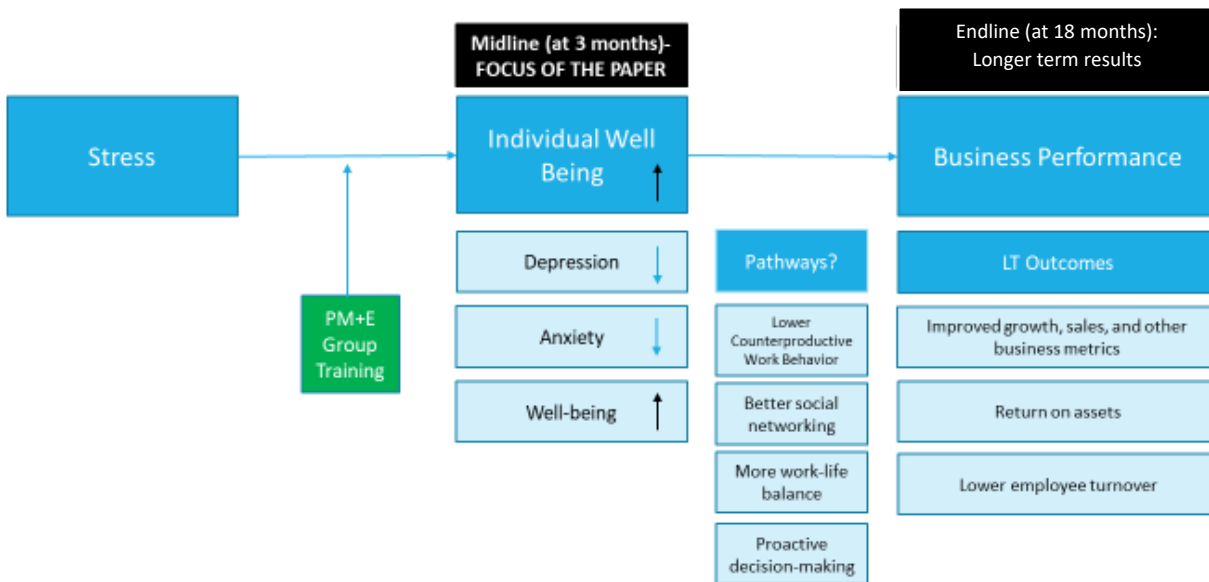
4. Theory of Change and Key Outcomes

It is hypothesized that the PM+E intervention would improve mental health outcomes through reduced intensity and prevalence of depression and anxiety symptoms. Because mental health and well-being are intimately linked, concurrent improvements in well-being are expected as the mental health of entrepreneurs improves. Over time, this would lead to better business performance, such as increased sales, reduced employee turnover, and lower absenteeism rates within the firm. These tangible improvements at the firm level are likely to be mediated by a

number of potential impact pathways (or pro-adaptive behaviors), which enable entrepreneurs to be more productive in the workplace. While the current literature does not provide concrete evidence on the types of pro-adaptive behaviors that facilitate improvements in business performance of SME entrepreneurs in FCV environments, it is hypothesized that these would include behaviors such as better social networking, lower counterproductive work behavior, better work-life balance that prevents burnout, and proactive decision-making (see Figure 2).

In this sense, the theory of change posits that improved individual mental health (as measured by a reduction in the prevalence and intensity of depression and anxiety symptoms) and, relatedly, improvements in well-being, will result in improved business performance via pro-adaptive behaviors.

Figure 2: Theory of Change



Source: Saraf, 2019

Since changes in firm performance take longer to manifest, the primary focus of this midline report is improvements in the intensity and prevalence of depression and anxiety symptoms. This was measured using the Patient Health Questionnaire- Anxiety and Depression Scale (PHQ-ADS), where a score of 10 or above indicates prevalence of anxiety and depression (ranging from mild to severe). A secondary, but closely related outcome variable, is well-being, measured by the WHO (Five) Well-being Index (WHO-5). In addition to these key variables, the study also measures additional variables at both baseline and the subsequent rounds to understand some current behaviors of entrepreneurs and, eventually, to shed light on the pathways through which improved mental health and well-being could lead to better business performance. At this juncture, business performance indicators are not reported. These variables will be collected during the endline survey. See Annex 3 for details on short-term and long-term business-relevant outcome measures that will be used to assess the results of the interventions.

5. Sample and Experiment Design

The 2012 World Bank Group-supported Economic Revitalization of KP and FATA (ERKF) project provided a unique setting to compare individuals who received a cash grant to rebuild or establish businesses in the conflict-affected area with individuals who received both a grant and the 5-week PM+E training intervention. This allowed for the testing of the hypothesis that financial assistance coupled with the psychosocial training would be more effective than just receiving cash grants in reducing depression and anxiety, the most common manifestations of psychosocial distress.

5.1 Sample Size Calculations

The unit of randomization in the study was individual entrepreneurs, with an equal number of entrepreneurs randomized into the intervention and control groups. The sample size was estimated using a recent study that measured changes in the occurrence of depressive symptoms as measured by the PHQ-9 (as a proxy for the PHQ-ADS, which has not been applied in similar contexts). The study utilized a sample of primary care (clinical) participants in the same area of Pakistan that showed a similar PM+ intervention had an effect size of 0.725 with a PHQ-9 total score as the outcome. An effect size which is one-third of the precedent effect size was assumed because the current sample was not derived from a clinically-referred population. Factoring this in, a 20 percent reduction (roughly, one-third of 0.725) in the occurrence of psychological distress was considered meaningful.

Power calculations suggested a minimum sample size of 84 participants per arm (power = 0.90; $\alpha = .05$, 2-sided). To account for a 25 percent attrition at the 3-month follow-up, a total of 235 participants were included and randomized into intervention (n=118) and control (n=117) arms (Saraf, Rahman, Hamdani, Jamison, and others, 2018).

5.2 Sample, Recruitment, and Data

A sample of 235 SME entrepreneurs was drawn from among beneficiaries of the ERKF cash grants program. All participants received a cash grant of 2 million Pakistani Rupees (PKR) (approximately US\$14,300) from ERKF for rehabilitation of their businesses. Participants were invited to join the training program from different locations of KPK, and were between 21 to 80 years of age. The majority (95 percent) of the entrepreneurs in the sample were male, which is representative of the ERKF beneficiary pool.

Data were collected on psychological indicators of study participants across three rounds. All data were conducted via telephonic interviews. The baseline survey was conducted prior to the start of the intervention, the first midline survey immediately after delivery of the intervention (at the 5-week mark), and a follow-up midline survey 3 months after the intervention via telephonic interviews. An endline survey is scheduled to be completed 18 months after the intervention.

5.3 Randomization

Effectiveness of the intervention was evaluated using an RCT. Following the baseline survey, recruited participants were randomized into intervention (n=118) and control (n=117) groups by an independent researcher. The intervention group received cash grants plus the 5 weekly face-to-face group sessions of the PM+E training intervention, while the control group received cash grants only.

5.4 Descriptive Statistics at Baseline

Majority of the participants (95 percent) were male and married (90 percent), with around 11.3 years of education on average. Average household income was PKR 101,291 (US\$ 725), and average number of dependents was 10. Fewer than half of the entrepreneurs (40 percent) received funding from ERKF during the first round of ERKF cash grants (1 year before the intervention), while the remaining received grants during the second round (6 months before the intervention). The largest proportion of firms owned by these entrepreneurs (36 percent) belonged to the service sector, followed by manufacturing, retailing, etc. Most firms (87 percent) were microenterprises (that is, having full-time employees of ≤ 20). Overall, the sample selected was representative of the larger population of ERKF grantees.

Tables 1-3 below show the demographic, business, and psychological characteristics of participants across the treatment and control groups at baseline. Demographic characteristics of participants across the treatment and control groups were well balanced at baseline. Psychological indicators at baseline suggest that 1 in 3 to 4 entrepreneurs were experiencing mild to severe symptoms of depression or anxiety at baseline (i.e. PHQ-ADS score of 10 or higher). These were balanced at baseline. Participants in the treatment group appear to have marginally higher well-being scores at baseline, with the difference statistically significant at the 10% level.

Table 1: Demographic Characteristics of Participants

Variable	Control		Treatment		t-test p-value
	N	Mean/SE	N	Mean/SE	
Male	117	95.7% [0.019]	118	94.1% [0.022]	0.566
Age (years)	116	42.9 [0.987]	118	42.2 [0.992]	0.604
Married	117	90.6% [0.027]	118	88.1% [0.030]	0.542
Education (years)	117	11.6 [0.329]	117	11.0 [0.418]	0.298
No. of dependents	109	10.5 [0.642]	113	9.5 [0.882]	0.372
Household income (PKR)	101	109,485 [12,880]	102	93,176 [9712]	0.312
ERKF Round 1	117	41% [0.046]	118	38.1% [0.045]	0.6522

Note: Standard errors in brackets. The values displayed for the t-tests are the p-values of difference across the groups. ***, **, and * indicate significance at the 1, 5, and 10 percent levels, respectively.

Source: Saraf, 2019; World Bank Group, 2018

Table 2: Business Characteristics of Participants

Variable	Categories	Control (%)	Intervention (%)	X ²	p-value
Business sectors	Manufacturing	33.3%	31.4%	4.911	0.427
	Retailing	13.7%	17.0%		
	Services	12.9%	17.8%		
	Wholesale	5.1%	6.8%		
	Other	35.0%	27.1%		
Size	Micro (0-20)	86%	88%	1.131	0.770
	Small (21-50)	7.6%	7.7%		
	Medium (50+)	5%	4%		

Note: The value displayed for the t-tests are the p-values of difference across the groups. ***, **, and * indicate significance at the 1, 5, and 10 percent levels, respectively
 Source: Saraf, 2019; World Bank Group, 2018

Table 3: Psychological Characteristics of Participants

Variable	Control		Treatment		t-test
	N	Mean/SE	N	Mean/SE	p-value
PHQ-ADS score	117	7.215 [0.816]	118	6.678 [0.769]	0.639
PHQ-ADS prevalence	117	29.9% [0.043]	118	22.0% [0.038]	0.170
Transformed WHO-5 score	116	77.931 [1.984]	117	82.393 [1.786]	0.096*

Note: The value displayed for t-tests are the p-values of difference across the groups. Standard errors in brackets. ***, **, and * indicate significance at 1, 5, and 10 percent levels respectively.
 Source: Saraf, 2019; World Bank Group, 2018

5.5 Intervention Implementation, Take-up, and Attendance Rates

A total of 118 participants received the intervention in 12 groups at 9 locations. Training was organized in the form of `affinity groups` based on the gender and location of the participating entrepreneurs based on inputs from the rapid needs assessment. Fourteen trainers participated in the *training of trainers*, and each group (with 10 participants on average) was led by one of these trainers and a co-facilitator. The five interactive sessions were, on average, approximately three hours each.

Overall, workshop attendance exceeded the usual rates seen in FCV contexts.⁶ However, attendance was lower than the assumed 75 percent, with 63.5 percent of the 118 participants

⁶ Typically, due to implementation challenges, attendance rates are rarely above 50 percent for interventions carried out in emergency areas.

attending 3 or more sessions. The median number of workshops attended was 3 (mean 2.6; SD 1.8), which is considered to be the critical number of sessions for PM+ training consideration. While attrition was higher than expected due to a religious festival and security episodes, there was no significant difference in the attrition rates between treatment and control group participants (see Annexes 4 and 5 for details of the full flow of participants from invitation to recruitment to allocation and data collection and analysis of attrition).

5.6 Empirical Specification

The causal impact of the intervention on primary outcome indicators was estimated separately across the two time periods, that is, immediately after the intervention at 5 weeks, and then 3 months after the intervention. The ‘Intent to Treat’ (ITT)⁷ effect on outcomes, Y , was estimated using an analysis of covariance (ANCOVA) specification to maximize power. Logistic regressions were used for binary outcomes. The estimation specification took the following form:

$$(i) \quad Y_i^E = \alpha_i + \beta_1 Treatment_i + X_i\lambda + \delta Y_i^B + \varepsilon_i,$$

where $Treatment$ indicates random assignment to the treatment arm. Y_i^B is the baseline value of the outcome indicator Y . Baseline characteristics, X , are also controlled for, including age, ERKF funding round, and level of education.

To maximize the small sample size, impact was also estimated using the following *pooled* specification using panel data:

$$(ii) \quad Y_i^E = \alpha_i + \beta_1 Treatment_i * Round_i + X_i\lambda + \delta Y_i^B + \varepsilon_i,$$

Where, $Treatment * Round$ indicates random assignment to the treatment arm in Rounds 2 and 3. As before, baseline characteristics, X , include age, ERKF funding round, and level of education, and Y_i^B is the baseline value of the outcome indicator Y .

Once again, logistic regressions were used for binary outcomes. Pooled regressions with standard errors clustered at the individual level are also estimated.

6. Results

This section summarizes the effect of the intervention on the primary (depression and anxiety symptoms) and secondary (well-being) outcomes at the midline time points. Business performance improvements, which are expected to take longer than 3 months to manifest, will be measured and analyzed following the endline survey. All results are analyzed by individual round (at the 5-week mark, immediately post-intervention, and at the 3-month mark) as well as by pooling data across both rounds. Results are captured at the outcome level for PHQ-ADS scores and prevalence (using odd-ratio). More details and direct accounts of beneficiary feedback can be found in Chapter 8 of the main report (Saraf, 2019).

⁷ Intention to Treat (ITT) analysis includes every subject who is randomized according to the randomized treatment assignment. This means that once all the participants are randomized into intervention and control groups, all the participants are included in the analysis regardless of if they complete the end-point or not (Gupta 2011).

6.1 Depression and Anxiety (PHQ-ADS)

6.1.1 PHQ-ADS Score (Intensity)

The Patient Health Questionnaire- Anxiety and Depression Scale (PHQ-ADS)⁸ is a measure where a score of 10 or above indicates prevalence and levels of anxiety and depression. Lower PHQ-ADS scores, therefore, indicate lower intensity of experiencing symptoms of anxiety and depression. Intent-to-treat (ITT) estimates show that entrepreneurs in the treatment arm have PHQ-ADS scores 0.74 lower than the scores of SME entrepreneurs in the control group at the 5-weeks (from a baseline average of 6.94). At the 3-month mark, the PHQ-ADS score for the treatment arm entrepreneurs goes down even more- by 1.36- relative to the control group. This suggests that intensity or level of depression and anxiety reduced for entrepreneurs in the treatment arm compared to the control arm, and the results improved over time. The 3-month results are statistically significant at the 10% level ($p=0.087$). Table 4 reports the Intention to Treat (ITT) estimates of the effect of the intervention on PHQ-ADS scores.

This also holds true when results are pooled across both rounds. On average, those in the treatment group experience a 1.07 reduction in PHQ-ADS score relative to the control group. The effect is statistically significant at the 10% level ($p=0.057$). When standard errors are clustered, results are not statistically significant.

Table 4. Impact of Treatment on PHQ-ADS Score

	(1)	(2)	(3)	(4)
	ANCOVA		Pooled	
	5 weeks PHQ-ADS score	3 months PHQ-ADS score	Pooled PHQ-ADS score	Clustered SEs PHQ-ADS score
Treatment	-0.736 (0.801)	-1.358* (0.788)	-1.070* (0.560)	-1.070 (0.672)
Baseline score	0.434*** (0.0460)	0.429*** (0.0457)	0.432*** (0.0323)	0.432*** (0.0591)
Round- ERKF	1.249 (0.826)	-0.714 (0.830)	0.309 (0.583)	0.309 (0.635)
Age	-0.00995 (0.0383)	-0.0197 (0.0374)	-0.0153 (0.0267)	-0.0153 (0.0308)
Education	0.0326 (0.0991)	0.00303 (0.0984)	0.0164 (0.0696)	0.0164 (0.0858)
Constant	1.604 (2.178)	3.149 (2.164)	2.430 (1.530)	2.430 (1.967)
Observations	206	200	406	406

Note: Standard errors in parenthesis.

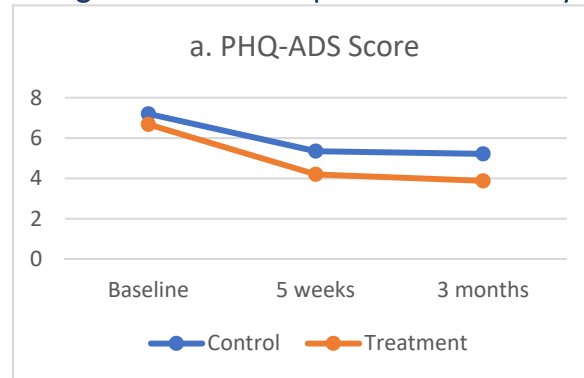
⁸ PHQ-ADS is a measure where a score of 10 or above indicates prevalence and levels of anxiety and depression. It is a composite measure of PHQ-9 (depression) and GAD-7 (anxiety). The PHQ-9 measures whether a person had difficulty in sleeping, felt hopeless/down, felt tired, had trouble falling asleep, had poor appetite, felt bad about him/herself, had difficulty concentrating, had been slow or restless, and had suicidal thoughts. The GAD-7 measures whether a person felt nervous or anxious, could stop worrying, worried too much, had trouble relaxing, was very restless, became easily irritable, and felt afraid about bad things happening.

Column 4 shows results of pooled regression with standard errors clustered at the individual level

*** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$

Source: Saraf, 2019; World Bank Group, 2018

Figure 3. Changes in Scores of Depression and Anxiety Symptoms



Source: Saraf, 2019; World Bank Group, 2018

6.1.2 PHQ-ADS Odds-Ratio (Prevalence)

Prevalence of depression and anxiety symptoms in the study population is measured by the proportion of respondents with PHQ-ADS scores greater than or equal to 10, which is indicative of whether someone is experiencing these symptoms for more than 3 days during the previous 2 weeks. The prevalence of depression and anxiety symptoms was balanced between the treatment and control groups at baseline. Impact on prevalence is expressed in odds-ratios, which indicates the odds of an outcome occurring given a particular exposure (in this case, conditional on being in the treatment group), compared to the odds of the outcome occurring in the absence of that exposure (in this case, being in the control group).

Improvements are reflected in the lowered odds ratio of prevalence of depression and anxiety symptoms. Intention to Treat (ITT) estimates (see Table 5 below) show dramatically lower odds of individuals in the treatment group experiencing depressive symptoms relative to those in the control group at both the 5-week and 3-month post-intervention marks.⁹ Compared to SME entrepreneurs in the control group, those in the treatment group have 0.65 times the odds of experiencing depression and anxiety symptoms at 5 weeks, immediately after the intervention (Column 1). The effect is larger at 3 months post intervention, with those in the treatment group having 0.46 times the odds of experiencing depression and anxiety symptoms compared to those in the control group (Column 2).

⁹ The results show the odds of an outcome occurring given a particular exposure (in this case, conditional on being in the treatment group), compared to the odds of the outcome occurring in the absence of that exposure (in this case, being in the control group). An odds ratio of 1 means that a person will have the same odds of experiencing depression and anxiety symptoms irrespective of whether he/she belongs to the treatment or control group. By contrast, an odds ratio of x/y means that the odds of a person in the treatment group experiencing such symptoms is x/y times that of the odds of a person experiencing such symptoms in the control group.

This suggests that entrepreneurs in the treatment group are substantially less likely (half as likely) to experience depression and anxiety symptoms compared to those in the control group, and that the effects improve over time. In absolute levels of prevalence, this means that one-third more entrepreneurs in the treatment group experienced improved quality of life as a result of their improved mental health status compared to entrepreneurs in the control group. Even though the effects are substantial in size, they are not statistically significant in both the 5-week and the 3-month mark, likely due to the small sample size and higher than expected levels of attrition.

The results are confirmed by using the alternative approach of the pooled regression¹⁰ (Columns 3 and 4). Consistent with the earlier impact estimates, SME entrepreneurs in the treatment group have 0.56 times the odds of experiencing depression and anxiety symptoms compared to those in the control group. The effect is statistically significant at the 10% level ($p=0.054$) and remains statistically significant at the 10% level ($p= 0.097$) when standard errors are clustered at the individual level.

Table 5. Impact of Treatment on Prevalence

	(1)	(2)	(3)	(4)
	ANCOVA		Pooled	
	5 weeks PHQ-ADS prev.	3 months PHQ-ADS prev.	Pooled PHQ-ADS prev.	Clustered SEs PHQ-ADS prev.
Treatment	0.649 (0.252)	0.459 (0.219)	0.563* (0.168)	0.563* (0.195)
Baseline prev.	4.684*** (1.848)	11.04*** (5.301)	6.503*** (1.931)	6.503*** (2.215)
Round- ERKF	1.484 (0.584)	0.684 (0.345)	1.120 (0.341)	1.120 (0.385)
Age	1.004 (0.0186)	1.001 (0.0227)	1.002 (0.0143)	1.002 (0.0162)
Education	0.972 (0.0459)	1.009 (0.0610)	0.983 (0.0364)	0.983 (0.0413)
0.127***0.127**Constant	0.155 (0.158)	0.0759* (0.0986)	0.127*** (0.101)	0.127*** (0.120)
Observations	206	200	406	406

Note: Standard errors in parenthesis.

Column 4 shows results of pooled regression with standard errors clustered at the individual level

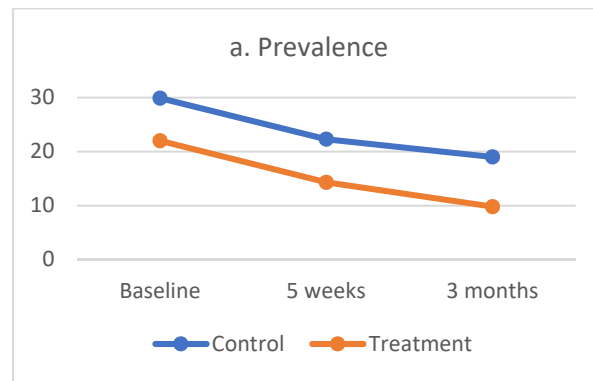
*** $p<0.01$, ** $p<0.05$, * $p<0.1$

Source: Saraf, 2019; World Bank Group, 2018

Figure 4 below show prevalence trends across the three rounds for all participants.

¹⁰ The pooled sample comprises of all respondents from both follow-up panels (i.e. 5 weeks and 3 months). Table 5, Column 3 shows the result of the pooled logistic regression, and Column 4 shows the same result after clustering standard errors at the individual level.

Figure 4. Changes in Prevalence of Depression and Anxiety Symptoms



Source: Saraf, 2019; World Bank Group, 2018

Looking at the movement of individuals across the four categories of severity measured by the PHQ-ADS (none, mild, moderate, and severe) provides a clearer picture of how these changes affect individual entrepreneurs at various points along the depression-anxiety spectrum. Table 6 (Columns 1-2) shows the changes across the severity categories between the treatment and the control group participants. This analysis suggests that the *treatment was most effective at improving outcomes for those at the margins or onset of depression and anxiety (that is, those in the “mild” category)*, as well as those *experiencing moderate levels of depression and anxiety*, the latter especially at the 5-week mark. This becomes clearer when data is restricted to only those entrepreneurs who were interviewed at all 3 rounds (columns 3 and 4). The proportion of treatment group entrepreneurs in the mild and moderate categories go from 19.3% at baseline to 8.2% at the 3 months mark, which is a substantial reduction. While reduction is also observed in the control group (from 24.2% to 17.6%), the percentage reduction is much smaller.

Table 6. Changes in Depression and Anxiety Category across 3 Rounds

Time-points	Categories	All		Restricted sample*	
		Treatment Group (1)	Control Group (2)	Treatment Group (3)	Control Group (4)
Baseline	None (0-9)	N, f (%)	N, f (%)	N, f (%)	N, f (%)
	Mild (10-19)	92(78.0)	82(70.1)	76(77.6)	66(72.5)
	Moderate (20-29)	15(12.7)	24(20.5)	12(12.2)	15(16.5)
	Severe (30-48)	8(6.6)	8(6.8)	7(7.1)	7(7.7)
5 weeks	None (0-4)	3(2.5)	3(2.6)	3(3.1)	3(3.3)
	Mild (5-9)	90 (85.7)	80(77.7)	86(87.8)	72(79.1)
	Moderate (10-14)	12(11.4)	16(15.5)	10(10.2)	12(13.2)
	Severe (15-19)	1(1.0)	7(6.8)	0 (0.0)	7(7.7)
3 months	None (0-4)	2(1.9)	0(0)	2(2.0)	0(0.0)
	Mild (5-9)	92(90.2)	81(81.0)	88(89.8)	73(80.2)
	Moderate (10-14)	5(4.9)	13(13.0)	5(5.1)	12(13.2)
	Severe (15-19)	3(2.9)	4(4.0)	3(3.1)	4(4.4)
		2(2.0)	2(2.0)	2(2.0)	2(2.2)

Note: * A total of 189 participants (98 in the treatment group and 91 in the control group were interviewed in all 3 rounds).

Source: Saraf, 2019; World Bank Group, 2018

This intra-category analysis seems to suggest that low-touch psychosocial intervention for entrepreneurs in FCV contexts might be most effective in cases of mild to moderate depression that may risk becoming chronic and severe distress in future. Such a diagnostic and preventative approach could result in significant health care cost savings, as well as improvements in business productivity.

6.2 Well-Being

At the baseline, personal well-being was high (with average WHO-5 score of 80). Despite this strong starting point, there were substantial improvements observed in well-being of SME entrepreneurs in the treatment group, especially 3 months after the intervention. Table 7 shows the ITT estimates of treatment effect on the WHO-5 score at 5 weeks and 3 months post intervention, as well as results of analysis using pooled data. At the 3-month mark, WHO-5 score among entrepreneurs in the treatment group is 4.73 higher on average compared to their counterparts in the control group (Column 2). The difference between the scores is statistically significant at the 10 percent level ($p=0.074$). Using pooled regressions, WHO-5 scores of entrepreneurs in the treatment group in 2.7 higher on average, though the effect is not statistically significant.

Table 7. Effect of Treatment on Well-Being

	(1)	(2)	(3)	(4)
	ANCOVA		Pooled	
	5 weeks WHO-5 score	3 months WHO-5 score	Pooled WHO-5 score	Clustered SEs WHO-5 score
Treatment	0.751 (2.147)	4.732* (2.637)	2.710 (1.698)	2.710 (1.958)
Baseline score	0.442*** (0.056)	0.338*** (0.067)	0.392*** (0.0436)	0.392*** (0.0580)
Round- ERKF	0.105 (2.197)	3.669 (2.742)	1.924 (1.750)	1.924 (1.845)
Age	0.134 (0.103)	-0.135 (0.125)	-0.00123 (0.0810)	-0.00123 (0.0926)
Education	-0.735*** (0.265)	-0.207 (0.327)	-0.480** (0.210)	-0.480** (0.212)
Constant	50.73*** (6.711)	60.76*** (8.144)	55.73*** (5.280)	55.73*** (6.675)
Observations	205	199	404	404

Note: Standard errors in parenthesis.

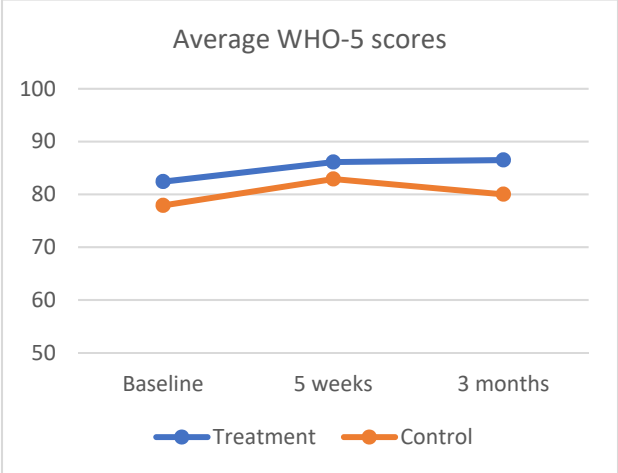
Column 4 shows results of pooled regression with standard errors clustered at the individual level

*** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$

Source: Saraf, 2019; World Bank Group, 2018

Figure 5 illustrates the improved trend in well-being observed among the treatment group participants relative to the control group participants. At the 5-week mark, positive trend is observed in the WHO-5 scores across both groups. At 3 months, the positive and increasing trend in personal well-being is maintained in the treatment group, whereas the control group experiences a decline. Entrepreneurs in the treatment group, therefore, experience improved well-being (that is, they are in good spirits, relaxed, engaged, and so on more often) as a result of going through the training program- months after the secession of the intervention.

Figure 5. Psychological Indicators Across the Treatment and Control Groups



Source: Saraf, 2019; World Bank Group, 2018

6.3 Discussion

Our results suggest that although cash transfers (with an average size of US\$14,300) may improve mental health by perhaps addressing financial constraints and related stress, combining it with a low-cost PM+E intervention (at a cost of US\$300/trainee) can further improve mental health (both prevalence and intensity of depression and anxiety) as well as well-being among SME entrepreneurs in FCV contexts. The odds of experiencing depression and anxiety for entrepreneurs in the treatment arm is substantially lower (0.46x) compared to the control group.

Across all outcome indicators, impact is larger 3 months after the intervention, compared to immediately after at 5 weeks. This suggests that benefits of a CBT-based training curriculum,

which focuses on changing mindsets (that is, developing positive outlook and resilience, and improving decision-making abilities), may be incremental over time. It also implies that the impact of psychosocial interventions, in general, on mental health and well-being may take a while to manifest, and impact evaluations need to factor that in.

Since this is one of the first studies looking at the impact of such an intervention on a non-clinical population, a proper benchmark for comparison does not yet exist. For instance, it was not possible to answer how a reduced odds ratio of 0.46 of encountering depression and anxiety compares to other interventions for entrepreneurs. However, consultations with clinical psychologists in Pakistan and at the University of Liverpool who have conducted PM+ RCTs suggest that a reduction of this magnitude in the prevalence and intensity of depression and anxiety symptoms is meaningful for a non-clinical population such as entrepreneurs. That the PM+E curriculum was able to move people across categories of depression and anxiety is also a test of clinical meaningfulness.

Given the challenging implementation environment, attrition levels were higher than anticipated which reduced the power to detect statistically significant impact with greater confidence. At the same time, with the existing sample size, the results show (clinically) meaningful and directionally expected results. Three months after the intervention, based on analysis of pooled data across two follow-up rounds, entrepreneurs in the treatment group experienced statistically significant reduction in the intensity and prevalence of depression and anxiety symptoms and higher levels of well-being compared with the control group. This implies that with a larger sample in future studies, these effects could be determined with greater confidence.

7. Conclusion

The project demonstrates that empirical research, including RCTs, can be conducted in challenging, FCV settings through appropriate rapid training of local researchers and NSPs. The ERKF project provided a unique setting for researchers to test the hypothesis that financial assistance, coupled with the 5-week PM+E training intervention, can be more effective at reducing psychological stressors of SME entrepreneurs in FCV contexts, such as symptoms of depression and anxiety — the most common manifestations of psychosocial distress.

The results of this study are encouraging for a few reasons.

First, it confirms that even non-clinical populations suffer from clinically significant levels of mental health issues such as depression and anxiety. The baseline data indicates that 1 of every 3 to 4 SME entrepreneurs in KPK experiences symptoms of depression and anxiety. This is new data and provides a sense of the gravity of the situation. It would help to make a case for mental health services to be made available for not only clinical populations, but also for populations at-risk, as per the Lancet Commission recommendations.¹¹ As such, it can also help to prevent burgeoning healthcare costs in the future, ensuring a decent quality of life for all.

¹¹ According to the Lancet Commission report on Global Mental Health (2018), policy makers and practitioners need to “broaden the global mental health agenda from a focus on reducing the treatment gap for people affected by mental disorders to the improvement of mental health for whole populations.”

Second, meaningful improvements in mental health were achieved, with improvements persisting, and indeed increasing, beyond the immediate post-intervention period. The intervention leads to reduced odds of experiencing symptoms of depression and anxiety (0.46 times the odds compared to the control group), and results in a statistically significant decline in the PHQ-ADS score of treatment group entrepreneurs compared to the control group when data is pooled across both rounds. Essentially, this reduces the prevalence rate in the treatment group by more than half. On intensity of occurrence, beneficiaries in the treatment group experienced statistically significant improvements compared to the control group, using pooled data.

Third, given the limited evidence base on the impact of psychosocial interventions on mental health for SME entrepreneurs, this study serves as a positive example of the feasibility of implementing such interventions in post-conflict and violence-affected contexts. The tool that was developed using existing literature and a rigorous mixed-methods approach can be applied to such environments to collect high quality information.

Finally, the intervention was delivered by NSPs, circumventing the need for scarce specialist resources. The cascade model of training and supervision can serve to train NSPs in other FCV-affected areas, not only for entrepreneurs but also for other beneficiary groups. The curriculum can be adapted to adult income-earner populations, as well as those affected by forced displacement. For example, teachers who are in the stressful and critical job of instructing in FCV contexts might benefit from such CBT-based training.

The intervention also revealed several limitations and constraints of implementing such programs and evaluations in challenging environments. The geographical spread and conflict persistence had an impact on attendance and attrition rates. Although the average attendance rate was above 60 percent, which is considered quite good for FCV contexts, it was lower than the 75 percent attrition anticipated by the team. These limitations in sample size most likely affected the ability to detect significant effects of the intervention on outcome variables such as prevalence, which only shows statistically significant effect when data is pooled across the two rounds, despite having large effect sizes using ANCOVA. This attendance and attrition rates could be improved in the future by focusing the training on specific groups of entrepreneurs. From this work, it appears that low-income entrepreneurs (as opposed to high income entrepreneurs) tend to attend diligently, probably because they lack substitute networks and resources to otherwise access such trainings. Larger sample size (calculated circa 630+) would allow to stratify randomization along critical characteristics in future studies.

Overall, the findings from this study introduce a novel and scalable method of implementing useful psychosocial training and conducting research in a challenging real-life setting. Positive trend in the results is promising and clinically important, and could be further built upon in larger studies in the future.

ANNEX 1. Rapid Needs Assessment Sample

Further details on the study sample

The sample of in-depth interviews (IDIs) for the Rapid Needs Assessment included SME entrepreneurs who were ERKF grantees. The ERKF employs the following selection criteria for its grantees: the SME entrepreneur is a citizen of Pakistan doing business in KPK or FATA, and employs a minimum of 3 and a maximum of 100 persons. The SME was doing business before the 2009-10 humanitarian crisis and his or her business was affected by the crisis. The SME is located in target sectors and locations supported by the project. The grants are used as working capital for reconstruction of basic infrastructure, and/or acquiring/repairing machinery and equipment. Over 90 percent of the recipients are male.

A sub-sample representative of ERKF grantees was selected. Utilizing a list of 34 SME entrepreneurs shared by the ERKF, 26 SME entrepreneurs from KPK and FATA were selected to participate in the IDIs. Of the 26 participants, 17 participants were interviewed (13 from Peshawar and 4 from Swat).

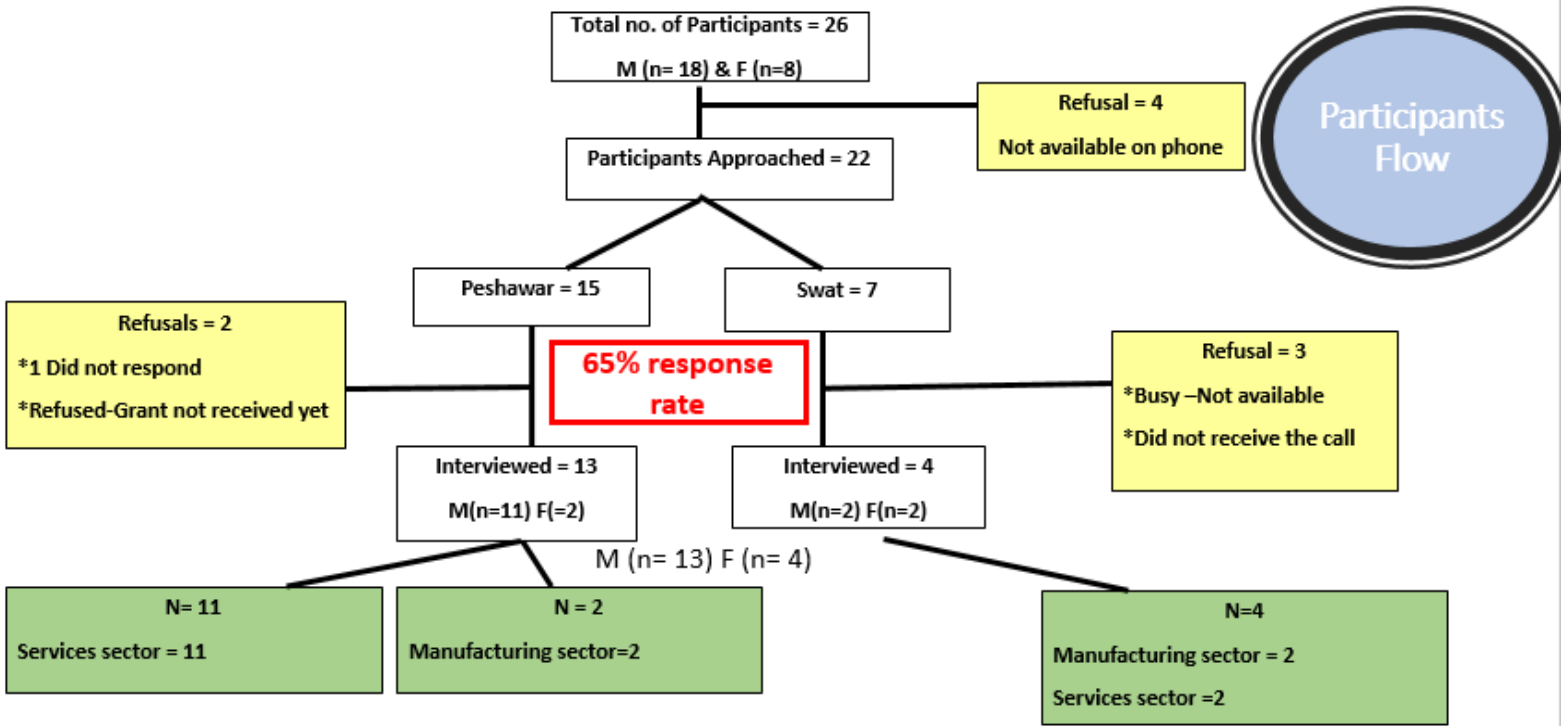
Two participants could not be contacted using the available contact details, and 7 participants could not be interviewed due to their unavailability and/or unwillingness to participate in the study (Figure 6).



Image 1: Rapid Assessment Study Sites

Source: World Bank Group, 2018

Figure 6: Participants Flow



Source: World Bank Group, 2018

ANNEX 2. Common Psychological Intervention Curricula

Table 8. Comparison of Common Psychological Intervention Curricula

Intervention	Standards Themes	Structure and Delivery
Cognitive Behavior Therapy (CBT)	<ol style="list-style-type: none"> 1. Recognizing automatic thoughts (understanding and identifying thoughts/ beliefs and subsequent reactions; thinking report) 2. Thinking of new ways to respond (slowing down automatic thought, alternative responses, responding to conflict, rational self-analysis). 3. Social mobilization (community connections, how actions affect others, decision-making scenarios) (CBT 2.0 Curriculum, Ideas42 and Crime Lab)	Group or individual; repeated long-term session (3-4 months), also utilizing feedback and homework; delivered in-person, in groups, over the phone, internet, videos, and so on; mostly delivered by trained facilitators with varying levels of expertise.
Mindfulness-based cognitive therapy (MBCT)	<ol style="list-style-type: none"> 1. Awareness and automatic pilot 2. Living in our heads 3. Gathering the scattered mind 4. Recognizing aversion 5. Allowing/letting be 6. Thoughts are not facts 7. Taking care of self 8. Maintaining and extending new learning (Segal, Williams and Teasdale 2013)	Eight weekly group sessions of approximately 2 hours each, plus a 6-hour practice session; individual daily homework in between sessions; can be delivered online or through trained facilitators.
Rational Emotive Behavior Therapy (REBT)	<ol style="list-style-type: none"> 1. Activating event 2. Beliefs (rational and irrational) 3. Consequences 4. Disputing irrational thoughts/feelings 5. Effective adaptation (David and others 2005)	Adaptable: individuals, couples, families or groups; facilitated by trained therapists; a higher number of sessions is better.
Problem Management Plus (PM+)	<ol style="list-style-type: none"> 1. Managing stress 2. Managing problems 3. Get going, keep doing 4. Strengthening social support #All based on CBT core principles (WHO 2016)	Five weekly group of individual sessions of 90 minutes and 3 hours each, respectively; can be adapted for groups; delivered by trained, lay-persons, that is, non-mental health specialists.
Personal Initiative Training (PIT)	<ol style="list-style-type: none"> 1. Self-starting behavior 2. Innovation, identification and exploitation of opportunities 3. Goal-setting 4. Access to finance 5. Planning 6. Feedback 7. Overcoming obstacles 8. Individual project (Campos and others 2018)	Twelve half-day group sessions across four weeks; 36 hours of instruction; group and individual components; individual component includes in-person mentoring for four months; and three-hour long business visits by trainers.

Source: Adapted from Saraf and others (2018)

ANNEX 3. Outcome Measures

Primary Indicators

Depression and anxiety: The primary outcomes are the prevalence and intensity of depression and anxiety symptoms, as measured using the Patient Health Questionnaire Anxiety-Depression Scale (PHQ-ADS), which combines the 9-item Patient Health Questionnaire (PHQ-9) and the 7-item Generalized Anxiety Disorder (GAD-7) scales (Kroenke and others 2016; Chilcot and others 2018). The PHQ-9 incorporates Diagnostic and Statistical Manual of Mental Disorders (DSM)-Version IV depression diagnostic criteria with other major depressive symptoms (Kroenke and others 2001). Participants rate their responses on a 4-point Likert scale ranging from 'not at all' to 'nearly every day' (0-3), with the score ranging from 0 to 27. It measures whether a person had difficulty in sleeping, felt hopeless/down, felt tired, had trouble falling asleep, had poor appetite, felt bad about him/herself, had difficulty concentrating, had been slow or restless, and had suicidal thoughts. The GAD-7 is based on the DSM IV diagnostic criteria for generalized anxiety disorder and has 7 items (Spitzer and others 2006). As with the PHQ-9, each item is scored on a 4-point Likert scale ranging from 'not at all' to 'nearly every day' (0-3), with the score ranging from 0 to 21. The GAD-7 measures whether a person has not been able to control worrying, has trouble relaxing, feels nervous and on the edge, is easily irritable, feels afraid that something terrible might happen, etc. The PHQ-ADS score is calculated as the sum of the PHQ-9 and GAD-7, with the total score ranging from 0 to 48. Higher scores indicate higher intensity. The cutoff scores of 10, 20, and 30 indicate mild, moderate, and severe levels of depression and anxiety, respectively.

The Cronbach's Alpha scores of PHQ-9 and GAD-7 scores show strong internal consistency, with scores above 0.8 across all three rounds (see Table 9). The overall PHQ-9 and GAD-7 scores also appear to be highly correlated.

Table 9. Reliability of PHQ-ADS score

	Cronbach's Alpha*	Correlation
Baseline	0.8449	0.7402
5 weeks	0.8232	0.7009
3 months	0.8348	0.7184

Source: Saraf, 2019

Secondary Indicator

Well-being: This was measured using the WHO-5 Well-Being (WHO-5) index (Topp and others 2015). The WHO-5 is a short, generic global rating scale measuring subjective well-being. The respondent is asked to rate how well each of the 5 statements applies to him or her when considering the previous 14 days. Each of the 5 items is scored from 5 ('all of the time') to 0 ('none of the time'). The raw score ranges from 0 (an absence of well-being) to 25 (maximal well-being). Scores are then converted to a percentage scale from 0 (absent) to 100 (maximal). The WHO-5 measures whether a person reports feeling cheerful and in good spirits, calm and relaxed, active and vigorous, fresh and rested, and values their daily life.

Mediating Variables

These are variables that might facilitate improvements in business performance as a result of improved mental health and well-being of entrepreneurs. They include counterproductive work behaviors (CWB), social networking, perceived social support, individual entrepreneurial orientation (autonomy, risk taking, proactive decision making, information seeking, and so on), as well as overall work-life balance. A brief description of each is provided below.

- **Perceived social support** was measured using the Multi-dimensional Scale for Perceived Social Support (MSPSS). MSPSS measures perceived social support in three domains: family, friends and significant others (4 items each).
- **Psychological capital** was measured using the Psychological Capital Questionnaire (PCQ) 12 items version. The PCQ-12 measures psychological capital across four domains (hope-4 items, optimism-2 items, resilience 3 items and self-efficacy-3 items).
- **Individual Entrepreneurial Orientation (IEO)** was measured using an adapted Individual Entrepreneurial Orientation (IEO) Scale (Sang and Lim 2009). Data were collected regarding the autonomy, innovativeness, risk taking, competitive aggressiveness, information seeking (pro-active behavior) and impulsiveness to reflect the degree of change in behaviors over time.
- **Social networking** was measured using the composite scores of social networking with other business circles, as measured by the 4-item Social Networking Questionnaire. The questionnaire tapped into 4 areas of entrepreneurial networking: 1) sharing of business ideas, new techniques or suppliers; 2) formation of connections with new potential customers, markets or other entrepreneurs; 3) gain of new customers, or financial support from other entrepreneurs; and 4) Sharing of tools, inputs, equipment or employees with other entrepreneurs.
- **Work-life balance (WLB)** was measured using the composite scores of work-life balance as measured by the 8-item Work-life Balance Questionnaire. WLB is described in the current study as the balance that an individual requires between the time allocated for work and other aspects of life.
- **Counterproductive work behavior (CWB)** was measured using the composite score of counterproductive work behaviors as measured by 4 counterproductive work behavior questions. CWB is non-productive behavior of entrepreneurs that goes against the legitimate interests of an organization. As such, it can harm organizations or people in organizations, including employees and clients, customers. Entrepreneurs were asked whether they thought they should have stayed home, had angry outbursts, complained about insignificant things at work, or thought of leaving the business in the previous three months.

Business Performance Variables: Sales, asset turnover, employee turnover etc.

Since improvements in mediating variables and business performance are likely to take longer to manifest, these outcome variables will only be measured at endline.

ANNEX 4. Attendance

A total of 118 participants received the intervention in 12 groups at these locations: Peshawar (3 groups), Swat, Nowshera (2 groups), and Charsadda, Hangu, Bannu, Naraan and Dir (1 group each). A total of 14 trainers participated in the *training of trainers* workshop. The training was delivered face-to-face in a group format, with an average group size of 10 participants. Each group was led by the trainer and a co-facilitator, who supported with logistics, group management, and group activities. The 5 interactive sessions were, on average, approximately three hours each.

Figure 7. Study Site Provinces in Pakistan



Source: Saraf, 2019

The workshop participants represented a very heterogeneous group of SME entrepreneurs with respect to key variables, such as age, socioeconomic status, educational background, business sectors, knowledge, skills and experiences, scale of operations, annual turnover, number of

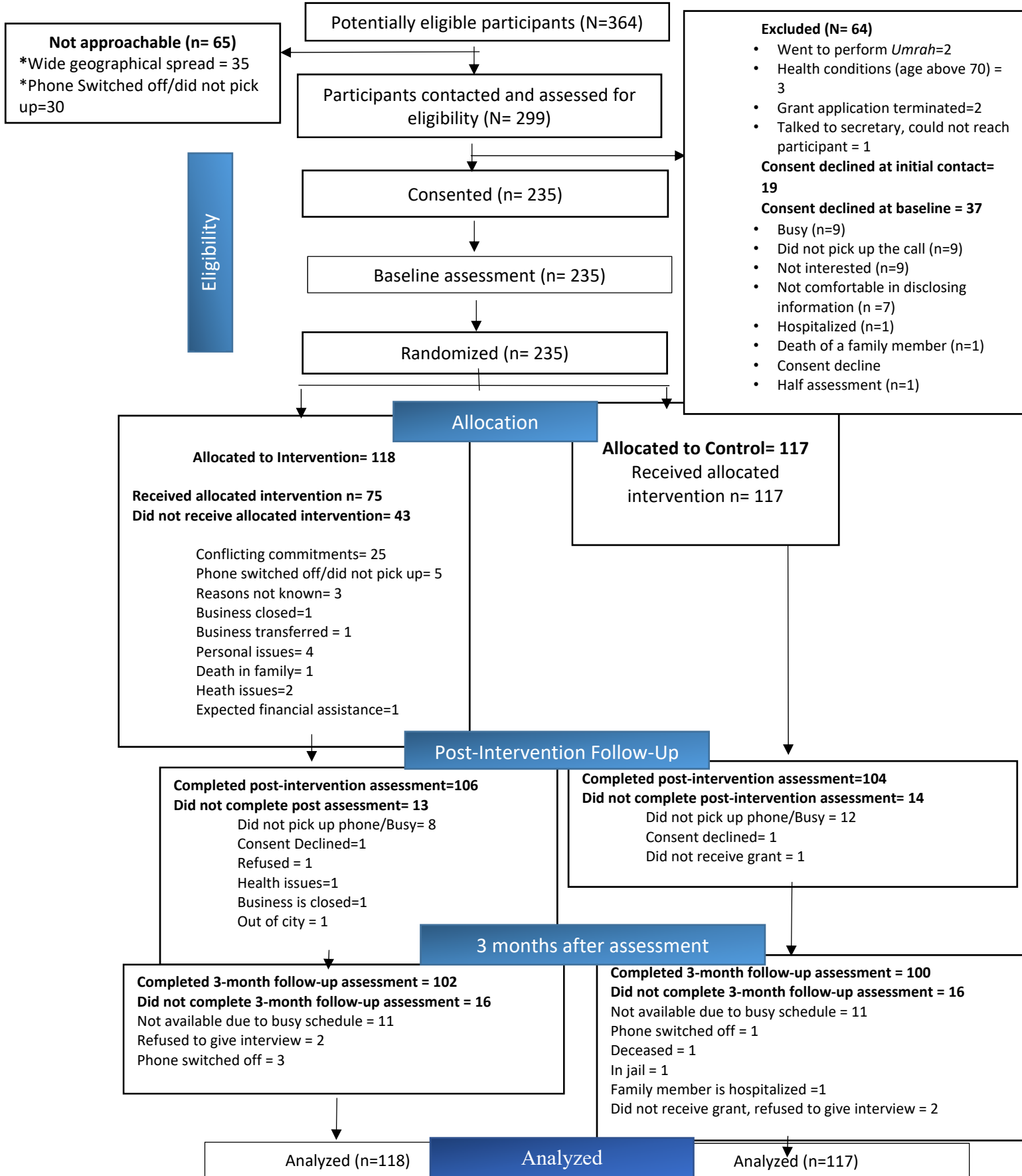
employees, and geographical locations. To cater to this heterogeneity, the training was organized in the form of *'affinity groups'* based on the gender and location of SME entrepreneurs. Since the geographical spread of ERKF grantees was wide, the training was organized at venues convenient for the participants. Indeed, some of sessions were organized at the business sites of entrepreneurs. Separate training groups were organized for male (n=11 groups) and female (n=1 group) SME entrepreneurs.

Overall, attendance at the intervention workshops was satisfactory, exceeding the usual rates seen in FCV contexts due to the challenges of implementation.¹² However, they were lower than 75 percent, which was assumed during the sample size calculation. Seventy-five (63.5 percent) of the 118 participants attended 3 or more sessions, 19 (16 percent) attended 2 or less, and 24 (20 percent) did not attend any sessions. The median number of workshops attended by the participants was 3 (mean 2.6; standard deviation [SD] 1.8), which is considered to be the critical number of sessions for PM+ training consideration. Details of the full flow of participants from invitation to recruitment to allocation and analysis are in Figure 8.

The heterogeneity among participants appeared to influence their engagement and participation in the training. For example, most participants from urban areas such as Peshawar were high-end entrepreneurs, with higher educational backgrounds and advanced business skills. Such participants were extremely busy and found it difficult to commit to the training amid competing business demands. On the other hand, participants who operated small businesses and belonged to lower socioeconomic strata and geographical areas, which were directly impacted by humanitarian crises such as Dir and Charsadda, had the highest participation rates. This provides useful insight about what kind of entrepreneurs could benefit more/most from such programs.

¹² Typically for interventions carried out in emergency areas, attendance rates are rarely above 50 percent.

Figure 8: Flow of Study Participants



ANNEX 5. Attrition

A simple comparison of attrition between the treatment and control group participants suggests that there were no significant differences in the rates of attrition between the two groups, that is, being in the treatment group did not significantly increase or decrease the likelihood of attrition in subsequent rounds.

Table 10a: Comparison of Attrition

VARIABLES	(1)	(2)
	5 weeks	3 months
Treatment	-0.00949 [0.0418]	-0.00971 [0.0455]
Constant	0.120*** [0.0296]	0.145*** [0.0323]
Observations	235	235
Adjusted R-squared	-0.004	-0.004

Standard errors in brackets

*** p<0.01, ** p<0.05, * p<0.1

Source: Saraf, 2019; World Bank Group, 2018

Analysis of differential attrition (which assesses if attritors in the treatment group have different baseline characteristics compared to attritors in the control group) shows that attritors in both groups are similar across key demographic variables- gender, education, ERKF funding round, household income (50,000 PKR or above), age, and number of dependents. The exceptions are marital status (i.e. whether married or not) and household income at the 5-week mark. Attritors in the treatment group were less likely to be married (difference of 38% percentage points; p=0.0087) and had much higher household income relative to those in the control group. Similarly, non-attritors in the treatment group had lower income relative to those in the control group. However, all difference across the two groups becomes statistically insignificant at the 3 months mark.

Table 10b: Differential Attrition

VARIABLES	Attrition=1		Attrition=0	
	(1)	(2)	(3)	(4)
	5 weeks	3 months	5 weeks	3 months
ERKF Round	-0.1648 [0.3219]	0.2096 [0.2400]	0.0561 [0.4144]	-0.0026 [0.9703]
Male	-0.0549 [0.7562]	0.0662 [0.5238]	0.0284 [0.1831]	0.0090 [0.7575]
Education	0.2418 [0.8779]	-0.1213 [0.9380]	0.5809 [0.3043]	0.6703 [0.2394]
Married	0.3846*** [0.0087]	0.0074 [0.9504]	-0.0211 [0.6082]	0.0276 [0.5222]

Household Income (PKR)	-80.719*	-4,667	28,408*	18,923
	[0.0788]	[0.9347]	[0.0986]	[0.2511]
Age	4.4560	2.9001	0.2908	0.4213
	[0.2541]	[0.3958]	[0.8458]	[0.7825]
No. of Dependents	1.1282	3.2667	0.9970	0.6212
	[0.6503]	[0.2114]	[0.4501]	[0.6077]

Columns show difference in means between treatment and control group

p-values in brackets

*** p<0.01, ** p<0.05, * p<0.1

Source: Saraf, 2019; World Bank Group, 2018

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