தமிழ்நாடு तमिलनाडु TAMIL NADU 67AB 308725

18/11/19 World Vision India

V. RAJENDRAN, B.A.,
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No.54/420, PANTHEON ROAD,
EGMORE, CHENNAI-600 008

Memorandum of Understanding (MoU)

This Memorandum of Understanding ("MoU") is entered into at Chennai on this...22nd... November 2019

Between

RADICALS (Reducing Adolescent Depression in India- Cultivating Adolescent Life Skills) project of World Vision India , a NGO registered under the Tamil Nadu Societies Registration Act, 1975 (herein after referred to as "WVI" which expression shall include its successors and legal assigns), having its registered office at No. 16, V.O.C Main Road, Kodambakkam, Chennai -600 024,

And

MADRAS SCHOOL OF SOCIAL WORK (herein after referred to as "MSSW" which expression shall include its successors and legal assigns), established in 1952, located in No. 32, Casa Major Road, Egmore, Chennai-600 008, South India, is an Autonomous Institution affiliated to University of Madras and NAAC accredited with Grade "A" in 2016.

Whereas World Vision India (WVI) is a humanitarian organization working to create a lasting change in the lives of children, families and communities living in poverty and injustice and serving all people regardless of religion, caste, race ethnicity or gender and as the proposed research will be involved in implementing the intervention program.

Whereas MSSW is an academic institution and Centre for Excellence in Health Studies of MSSW under which health research projects are carried by Department of Counselling Psychology and Post Graduate Department of Social Work. The team will support the design of studies, evaluate the intervention by conducting surveys at different stages during the project/research timeline and submit reports for the same.

This collaboration is voluntarily entered into between the Parties and the following terms and conditions shall govern the collaboration. It is effective from 1st Aug 2019 till 31st March 2020

Background: World Vision India has been actively engaged in addressing the issues of children in the country. Mental health issues of adolescents are increasing with diverse vulnerability factors for the children aged 10-19. In order to address this, sustainable strategy for mental health promotion for adolescents and addressing positive behavior change for mental health at school and household level are essential to address the issues of depression. Interpersonal Psychotherapy- Adolescent Skills Training (IPT-AST) is an innovative behavior change model, used in the US. World Vision India plans to implement this approach as a means to address depression among adolescents. This will be done in partnership with Greater Chennai Corporation (GCC) in educational institutions in all educational zones of Chennai Corporation. The overall aim of the RADICALS project is to assess and reduce sub clinical depression among 13-17 year adolescent boys and girls in Chennai Corporation Higher Secondary Schools (a proxy indicator for reduction of suicide rate) and study efficacy of IPT-AST in this context. Its specific objectives are:

1. To explore and identify social and demographic determinants of adolescent mental health.
2. To measure the sub clinical depression among the adolescents in Chennai Corporation Higher Secondary schools in Chennai.
3. To assess the level of social support of the adolescents in Chennai Corporation Higher Secondary schools in Chennai.
4. To assess self -efficacy of adolescents in Chennai Corporation Higher Secondary schools in Chennai.
5. To study the effectiveness of IPT-AST in reducing sub clinical depression among adolescents

For this, World Vision has decided to engage of an external agency to evaluate the model's effectiveness by looking at changes in the scores of screening tools for sub clinical depression.

RADICALS project has incorporated the vital components such as socio demographic indicators, social support system and self-efficacy component into the project cycle as a means evaluate the objectives of the research. MSSW is an autonomous educational institution established in 1952. It is the third best social service institution in the country. It has done many research projects with school children and has commendable relationship with the Government educational department. The institute serves in educating people in the field of social work and is all-inclusive in serving people regardless of race, caste or faith.

A. Key objectives of the partnership

1. To review the research and take into account potential risks and benefits for the community in which the research will be carried out with an ultimate goal to promote high ethical standards in research for health.

2. To evaluate the RADICALS project Operational Research in Chennai by conducting a base line, mid line and end line survey, along with a realist evaluation during the implementation of IPT-AST. MSSW will be responsible for translating the survey tools into Tamil, field testing the tools, identify and train data collectors, collect data and analyze the data. World Vision India will be the Principal Investigator for the research.

Duration: 20 months from 1st August 2019 to 31st March 2021.

B. Activities specific to the collaboration:

Both Parties agree that the below mentioned activities shall be implemented subject to the availability of funds with both the Parties and will strictly adhere to party specific deliverables only.

C. Terms and Conditions:

Key deliverables – From MSSW:

- Will provide need-based inputs into the research design.
- Support for trial roll out of IPT-AST based on need
- Will be responsible for translating the survey tools into Tamil and field testing the tools before carrying out data collection for any survey
- Will be responsible to recruit and train persons responsible for carrying out data collection as part of the evaluations
- Will carry out data collection in the intervention and control sites at different stages of the research
- Will monitor the survey and data collection once they have begun and, where relevant, take part in follow-up action will through, training and observation understand the IPT-AST model and the theory of change in which it operates
- Will be responsible for data entry in a password protected computer, data management, data cleaning and data quality of all data related to the evaluation
- Will submit reports of all the surveys and evaluations conducted to WV India within the timelines stipulated
- Will support engagements with GCC officials – Departments of Education & Health as per need
- Will support dissemination of the findings to GCC officials

#	Activity	Timeline	Deliverables
1	Sampling write up (Baseline, End line, process evaluation, obtaining permissions from the Government and other stakeholders	By December 31st, 2019	Finalized proposal with annexures
2	Finalize sample		List of sample schools
3	Translation of questionnaire		Draft of translated materials for review
4	Validation of tools	Jan 2020	Report of tool validation with data set and statistical results
5	Recruitment of data collectors/ Enumerators	April & May 2020	List of the names of data collectors/ Enumerators along with their educational qualifications and experiences
6	Training of data collectors	April & May 2020	Training report
7	Data Collection – Base line (Intervention)	From the subsequent week of training to four weeks after	Data set entered and scored
8	Data Collection – Base line (Comparison)	From the subsequent week of training to four weeks after	Data set entered and scored
9	Complete baseline report	4 weeks from completion of baseline data collection	Base line data collection report
10	Midline data collection for both intervention and comparison groups	November 2020 From the subsequent week of training to four weeks after	Data set entered and scored
11	Complete midline report	4 weeks from completion of midline data collection	Midline data collection report
12	Data Collection – End line for both intervention and comparison groups	February '21 From the subsequent week of training to four weeks after	Data set entered and scored
13	Complete End line report	In 5 days following data collection	End line data collection report
14	Consolidate OR report	Within 30 days from the end of data collection	Final OR report of the entire project

Key Deliverables World Vision India:

- Finalizing research design
- Getting permission from the schools both Chennai Corporation education department
- Submit the study for ethical clearance through World Vision India's Ethics review committee
- Conduct trial roll out of IPT –AST with need based support from MSSW
- Assist the data collectors in gaining access to the survey sites
- Rolling out the proposed Intervention phase
- Reviewing data collection, scoring and survey reports submitted by MSSW for quality (completeness and correctness)

- Coordinate regular meetings with MSSW team
- Ensure timely payments are made and all financial and legal requirements of WV India are adhered to.

Any deviation due to unavoidable circumstances need to be informed to either parties in advance and an alternate date as agreed upon both parties need to be honoured.

Data ownership and use: All data collected during this OR will be the property of World Vision India and all raw data will be handed over to WV India on conclusion of the project to authorised point person. MSSW will have access to the data for future studies and reference, with due approval in writing from WV India.

Cost: WVI will pay an amount of **INR 10, 46,000 (Rupees Ten Lakhs Forty Six Thousands)** inclusive of all charges for technical support and travel related costs. TDS as applicable. GST at 18% is applicable and will be over and above the cost mentioned. MSSW will share copy of GST registration.

Total cost including GST is **INR 12, 34,280 (Rupees Twelve Lakhs Thirty Four Thousand Two Hundred and Eighty)**

Payment Schedule:

a). World Vision India shall make payment only for the services delivered as per the approved proposal and schedule; and where required subject to testing and approving of the work rendered by MSSW for completeness and correctness. World Vision India shall not be responsible to make any payment or reimburse any costs/expenses incurred by MSSW for any service that has not been approved by WVI in writing.

b). TDS @10% will be deducted as per the government norms.

c). Payment shall be made as per the below agreed terms:

(i). 37% of the total payment after signing of MOU by both the parties and completion of first orientation program for World Vision project team and key functionaries.

(ii). 12% after submission of baseline report (June2020)

(iii). 8 % after the submission of midline survey report (November 2020)

(iv). 32% payment for end line survey (February 2021)

(v). 11% after the submission of final comprehensive report of quantitative end line evaluation (March 2021)

Compliance

MSSW is an independent entity. The execution of this MoU does not create any other relationship between MSSW and WVI nor provides MSSW and WVI a right to represent on behalf of the other party.

MSSW is solely responsible for the payment of all its statutory obligations and applicable taxes. TDS certificate will be issued by WV India

MSSW shall be solely responsible for their staff insurance coverage (medical, accident, travel, life, etc.) during the performance of services to WVI. WVI shall neither be responsible nor liable for any loss or damage, direct or indirect caused to MSSW staff or property during the performance of services under this MoU.

Confidentiality

MSSW agrees to not discuss its performance of services under this MoU with any third party without the prior written consent of WVI. MSSW may not use the data, results and/or findings for any educational purposes/research and publications without the consent or prior approval from World Vision India.

MSSW agrees to hold in confidence for the benefit of WVI any and all information which may be disclosed to it or to which it may have access, as a result of this MoU, including the results/final deliverables of the services hereunder.

MSSW shall not publish any document or in any way communicate to the press, media or public that has the effect of adverse criticism of any policy or action of WVI or that may be capable of embarrassing the relation between WVI and Persons, Institutions, Government with whom WVI has official dealings.

Use of Intellectual Property Rights (IPR) / Research Results:

World Vision India will be the sole owner of all data produced from research done within its projects. Thus, WV India shall retain a non-exclusive, free, irrevocable license to copy/use IP on Data for publishing, consistent with confidentiality arguments where-ever entered in the agreement.

Child and adult safe guarding Policy: (Annexure 1)

MSSW staff and volunteers engaged in the research adhere to World Vision's Child Protection Standards, Behavior Protocols, and/or Policies during the tenure of the assignment and any failure to adhere to the child protection measures will be regarded, as a breach of a material term of this MoU if presented with proven evidence and WVI shall have the right to immediately terminate this MoU without any further liability towards MSSW including that of payment for services rendered.

Assignment

MSSW shall not assign its rights or obligations under this MoU, in whole or in part, nor enter into any sub-contract arrangement to perform any portion of this Agreement, without the prior written consent of WVI.

Sensitivity & Protection of Identity

MSSW shall ensure that while providing the services under this MoU, the sensitivity to identity, culture, emotions, privacy, safety and well-being of the subjects/persons portrayed or involved or part of the final product/service shall be taken care of and at no point of time shall any

inappropriate photographs of any person especially a child or take any photographs/videos not commissioned to take as part of work order be taken.

MSSW shall be responsible and liable to make good any loss or damage or claim raised against WVI as a result of the performance of services by MSSW under this MoU.

Right to Works

MSSW agrees that all the Works along with underlying rights therein, generated for or during the performance of services in whatever stage of completion and all materials connected therewith including the final product/report under this MoU are works made for valuable consideration and are the property of WVI, and MSSW hereby assigns all rights, title and interest in and to such items to WVI.

Termination

Either Party shall have the right to terminate this MoU with mutual consent, by providing the other with thirty (30) days prior written notice of termination.

In the event of termination of this MoU on account of breach by MSSW of any of terms and conditions of this MoU, WVI shall be entitled to terminate this MoU immediately by giving a written notice of termination to MSSW and WVI shall not be liable to MSSW for any payment whatsoever to MSSW. However, MSSW shall be liable for any loss and / or damage incurred by WVI on account of such breach.

Force Majeure

In case of delay, damage, destruction or any other matters of that nature, arising out of circumstances such as war, rebellion, civil unrest, strikes, lock outs, industrial disputes, fire, earthquake, flood, riot, acts of God, and general shortages of energy and land or telecommunication access, the Affected Party shall forthwith notify the other Party in writing of any event likely to cause such failure or delay immediately. In such an event, the Affected Party shall use all reasonable endeavours to restore the performance of its obligations/exercise. In case, unable to proceed the Parties shall discuss and come to an amicable conclusion.

Entire Agreement

This MoU constitutes the entire agreement and understanding between the Parties, superseding all prior contemporaneous communications, representations, agreements, and understandings, oral or written, between the Parties with respect to the subject matter hereof. This MoU may not be modified in any manner except by written amendment executed by each Party hereto.

Dispute Resolution

All disputes arising out of or in connection with this Agreement shall be attempted to be settled through negotiation between senior management of both the Parties. If any Dispute arising between the Parties is not amicably settled within reasonable period of one month of commencement of attempt to settle the same, the Disputes shall be referred to arbitration under the provisions of the Indian Arbitration and Conciliation Act 1996 as amended from time to time. The parties agree (i) that the Arbitration proceedings will be conducted in Chennai and (ii) the panel of arbitration shall consist of three (3) members, one each appointed by the parties and the third appointed by the nominee arbitrators by consensus. (iii) The language of arbitration shall be English.

The Arbitral Award shall be conclusive, final and binding on the Parties.

Governing Law

This MoU shall be governed by and construed in accordance with the laws of India and the Courts at Chennai shall have exclusive jurisdiction in respect of disputes arising from or out of this MoU.

Severability

The Parties recognize the uncertainty of the law with respect to certain provisions of this MoU and expressly stipulate that this MoU will be construed in a manner that renders its provisions valid and enforceable to the maximum extent possible under applicable law. To the extent that any provisions of this MoU are determined by a court of competent jurisdiction to be invalid or unenforceable, such provisions will be deleted from this MoU or modified so as to make them enforceable and the validity and enforceability of the remainder of such provisions and of this MoU will be unaffected.

Notices

All notices, requests, demands and other communications under this MoU must be in writing and will be deemed duly given, unless otherwise expressly indicated to the contrary in this MoU: (i) when personally delivered; (ii) three (3) days after having been deposited in the mail, certified or registered, return receipt requested, postage prepaid; or (iii) one (1) business day after having been dispatched by a nationally recognized overnight courier service, addressed to a Party or their permitted assigns at the address for such Party first written above.

In witness whereof, the authorized signatories of both the parties hereto subscribe their signature as here under on this ...22nd November 2019.

Full Name: **Dr. Anjana Purkayastha**	Full Name: **Dr. S. Raja Samuel**
Position Title: **Senior Director –Special Projects**	Position Title: **Principal**
Signature: [signature]	Signature: [signature]
Date: 22/11/2019	Date: 22/11/2019
For and on behalf of **WVI**	For and on behalf of **MSSW**

Witnesses:

Full Name: D. DAISY	Full Name: P.K. VATHANI
Position title ADVOCACY SPECILIST	Position title: HOD - Asst Professor Dept of BSW, MSSW
Signature: [signature]	Signature: P.K. Vathani
Date: 25/11/19	Date: 22/11/2019
For and on behalf of **WVI**	For and on behalf of **MSSW**

Technical Proposal and Research Design
To assess the efficacy of Interpersonal Psychotherapy-Adolescent Skill Training (IPT-AST) in reducing sub clinical depression among adolescents in Chennai Corporation Higher Secondary schools.

Identification of sub clinical depression among adolescents of (13-17 age group) in Chennai Corporation Higher Secondary Schools and Intervention of IPT-AST to reduce the symptoms

I. GENERAL INFORMATION

Name of the Project:

Research study as a part of Reducing Adolescent Depression in India: Cultivating Adolescent Life Skills (RADICALS)

Name and Address of the Organization:

Madras School of Social Work
32, Casa Major Road
Egmore, Chennai – 600 008

Project Team

Dr. R. Subashini, M.Sc., Ph.D
Dr. C. Francis,M.A (SW).,MBA., Ph.D
Dr. Vyjayanthi Mala, M.Sc., Ph.D
Dr. Hannah John., M.Sc., Ph.D
Ms. Damen Queen., MSW., (Ph.D)

Contact Person:

Dr. C. Francis
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Madras School of Social Work, Egmore, Chennai – 600 008
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Research Contact:

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Madras School of Social Work, Egmore, Chennai – 600 008
Email: hannahjohn@mssw.in

Project Submitted To: World Vision India, Chennai

About Madras School of Social Work

MADRAS SCHOOL OF SOCIAL WORK (MSSW), established in 1952, located in No. 32, Casa Major Road, Egmore, Chennai-600 008, South India, is an Autonomous Institution affiliated to University of Madras and NAAC accredited with Grade A in 2016. The School is rated 3rd Best Social Work College in India and First in South India by Outlook Express in 2018. Madras School of Social Work was founded by Mary Clubwala Jadhav under the auspices of Madras State Branch of the Indian Conference of Social Work (renamed the Indian Council of Social Welfare) and the Guild of Service (central). The school is administered run under the aegis of the Society for Social Education and Research (SSER).

MSSW is offering regular courses Under Graduate and Post Graduate Courses in the following manner.

U.G courses - Bachelor of Social Work
- B.Sc Psychology,

P.G courses - Master of Social Work (MSW) specializing Human Resource Management, Community Development and Medical and Psychiatric Social Work,
- M.A-Human Resource Management,
- M.A- Human Resource and Organisation Development,
- M.A- Development Management,
- M.A- Social Entrepreneurship and
- M.Sc - Counselling Psychology.

In addition to this regular courses for the working professionals the following diploma courses are conducted

P.G. Diploma in HR&IR and
P.G. Diploma in Human Resource Management.

Departments Initiated to work for the Research Project

The Department of Counseling Psychology and the P.G. Department of Social Work of Madras School of Social Work have agreed to design and implement the research component of RADICALS project submit this joint proposal to World Vision India.

Introduction:

Adolescence is the transition period from childhood to adulthood, it refers to the age group from 10 to 19 years. This is the time when skills, behaviors and characters are formed, hence this phase needs more attention and guidance.[1] Around 16% which is 1.2 billion of world population are adolescents [2], more than half of them live in Asia in which 243 million live in India. [3] As adolescents continue their journey of self-discovery, they continually have to adjust to new experiences parallel to biological and social changes. This can be very stressful. A number of studies have indicated a high prevalence of mental health problems among students, including depression, compared to the rest of the population.[4]

World Health Organization (WHO) defines mental health as “a state of well-being in which every individual realizes his or her own potential, can cope with normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community”. Mental health is an integral part of health and it is more than presence of mental disorders. [5]

Mental health conditions among 10-19 years take 16% of the global burden of disease and injury. Moreover, 50% of all undetected and untreated mental health disorders in adulthood start by age 14. [6]

Of all mental health conditions, depression is the ninth leading cause of illness and disability among adolescents and in its worse it can lead to suicide. Suicide is the third cause of death in 15-19 year olds. In 2016, 62,000 adolescents died due to self-harm. Since 90% of the global adolescents live in low and middle income countries, 90% of the adolescent suicides can also be attributed as occurred from these countries.[6] Depression has a significant adverse impact on school performance, family relations, socialization, and increases vulnerability to future depressive episodes, substance abuse, suicide, psychosocial impairment and antisocial behaviours.[7–9] Evidences say that family and social support is associated with depression and act as protective factor for suicidal ideation. [10]

<u>Depression and suicide rates in India</u>

According to National Mental Health survey of India (2015-16), the prevalence rate of 0.8% of depression among 13-17 year old children. [11] With India witnessing significant changes (including globalization, urbanization, migration, and modernization) that is coupled with rapid sociodemographic transition, depression is likely to increase in the coming years. It is also acknowledged that depression influences the occurrence and outcomes of several diseases and conditions. Stress in the family and in the school is the major contributor to depression. Negative events and traumatic experiences, early relationship problems, educational setbacks, family history of mental illness and frequent migration were the associated factors for depression listed in an Indian study. [12] Recent Indian studies showed the prevalence around 25% mild and around 3% severe depression. Associated factors mentioned in these studies were locality (urban rural divide), abuse within and outside of the family, alcohol use/ smoking by the family member, lack of supportive environment in

school, spending less time in studies, academic stress, lower level of participation in cultural activities and relationship issues. Suicidal behavior is independently associated with factors such as absenteeism, independent decision-making, premarital sex, sexual abuse, physical abuse from parents, and mental disorders. Also, the proportion of girls affected with depression was higher than boys in Indian context. [13–15]

Depression and suicide rates in Tamil Nadu:

According to state mental health policy of India, the prevalence of mental health problems such as depression, anxiety disorders and substance use is 11.3%.[16] Suicide rates are high in India especially adolescent suicides are more. Mood disorders and substance use are identified as prime cause of suicides.[17] Studies done in India with varying context showed higher prevalence (Ranging from 10-40% to the maximum of around 70%) of depression.[18–20] Reported prevalence of 41% in a study conducted in four urban areas in India.[20] Around 50% prevalence reported in a study conducted in Chennai.[13]

Chennai being the capital of Tamil Nadu and most populous (around 7 million) city in the state with diverse socio-cultural, languages, economic and educational back ground. This gives the opportunity for the researchers to study the various determining factors of adolescent depression and this diversity provides the proxy setting for studying India.

Treatment for severe depression can be pharmacological, however psychotherapy is the choice for mild and moderate depression. Psychotherapies such as cognitive behavior therapy, mindfulness-based cognitive therapy and problem-solving therapies are the widely practiced.[21] Young et al in their trial conducted in United States found that enhancing interpersonal skills would have the positive effect on depression. Interpersonal psychotherapy with skill training had reduced depression significantly in their trial among adolescents.[22]

There is a large number of NGOs including World Vision India, working closely with Government with children addressing their health, education and nutritional needs. World Vision India which is present in Chennai city for about six decades is presently coordinating with Greater Chennai Corporation to address health needs of children and adolescents through various special interventions and projects. RADICALS is one of the projects of World Vision that focusses on adolescent mental health. World Vision has prioritized research in the field of mental health of adolescents through this project and will work with technical partner, Madras School of Social work for the research activities for the period of the study, with special focus on depression.

The primary objective is to assess the prevalence of sub clinical depression among 13-17 years adolescents in the government (corporation) schools of greater Chennai, and also to assess the efficacy of Interpersonal Psycho Therapy- Adolescent Skill Training (IPT-AST) model in reducing depression in Indian context among adolescents.

Methodology:

Aim:

To assess and reduce sub clinical depression among 13-17 year adolescent boys and girls in Chennai Corporation Higher Secondary Schools (a proxy indicator for reduction of suicide rate) and study efficacy of IPT-AST in this context.

Specific Objectives:

1. To explore and identify social and demographic determinants of adolescent mental health.
2. To measure the sub clinical depression among the adolescents in Chennai Corporation Higher Secondary schools in Chennai.
3. To assess the level of perceived social support of the adolescents in Chennai Corporation Higher Secondary schools in Chennai.
4. To assess the perceived self -efficacy of adolescents in Chennai Corporation Higher Secondary schools in Chennai.
5. To assess the efficacy of IPT-AST in reducing depression and in increasing the perceived social support and self-efficacy of adolescents in Chennai

Research hypothesis:

1. IPT-AST strengthens interpersonal relationships and psychosocial skills through which sub clinical depression is reduced among adolescents
2. IPT-AST strengthens interpersonal relationships and psychosocial skills through which self-efficacy and social support of adolescents is increased
3. The higher the social support, the lower the symptoms of subclinical depression
4. The higher the level of self-efficacy the lower the symptoms of subclinical depression

Research design:

The research design is Cluster Randomized Trial. This design allows the intervention to be rolled out in two different timeline for the clusters (inbuilt intervention and control groups) formed with in the participants receiving intervention. The steps involved in the research design are as follows:

Cluster: School

1. Research Cohort: Out of all higher secondary Corporation schools, 22 schools are coeducation schools and eligible to take part in the research. Among these schools, 10 schools are chosen purposively (one school from each educational zones) and

allocated into intervention group (Group A) and waitlisted control group (Group B) by cluster randomization (Lottery method) in which unit of randomization is schools.

2. Level 1 screening- Pre intervention screening for sub clinical depression for all the 9th and 11th standard adolescents in the purposively selected 10 schools using selective tools.
3. Intervention Phase 1- In this phase, the adolescents who are identified as having sub clinical depression in Group A will receive intervention whereas Group B will not receive any intervention and will act as waitlisted control group.
4. Level 2 screening includes post intervention screening for Group A and repetition of Pre intervention screening for Group B
5. Intervention Phase 2- After level 2 screening, the adolescents who are identified as having sub clinical depression in Group B will receive intervention whereas Group A remains as such without intervention.
6. Level 3 screening includes post intervention screening for Group B and repetition of post intervention screening for Group A.

Research design along with specific activities and timeline is as follows:

Month	PHASE		
	Pre-Trial Phase		
	WVI Deliverables		**Stakeholder Deliverables**
Nov-19			Finalize Research Design
Nov/Dec 2019	Hiring and Remote Training of Counsellors, Submit for Ethics Review Board		Finalize Translations
	Trial Phase		
Jan-20	Trail Baseline, Supervision		Trial baseline, Tool Validation
Jan to March 2020	Trial IPT AST Implementation, Supervision		
Mar-20	Register Under Clinical Trials		Trial End line
April/May 2020	Feedback and Modification		In-Person IPT-AST Training Refresher, Supervision
June to Sep 2020			
Jun-20	Baseline		
	Cohort 1	X	Cohort 2
Jun-20	Qualifies for Depressive Symptoms	x1	Qualifies for Depressive Symptoms
June to Aug 2020	Receives IPT AST (Intervention)	x1	Does not receive IPT AST / Receives Treatment-as-Usual for India via temporary school counselor (Control)
Oct-20	**Mid line 1/First Follow Up (after 3 months)**		
Oct-20	Received IPT AST (Intervention)	x2	Did not receive IPT AST / Received Treatment-as-Usual (Control)
Oct to Dec 2020			Provide IPT AST to Cohort 2
Feb-21	Second Follow Up for Cohort 1 (At 6 months)		First Follow up for Cohort 2 (after IPT AST)
Mar-21	**End line Final Follow up (@ 9 months for Cohort 1 and 6 months for Cohort 2)**		
	Received IPT AST	x4	Received IPT AST

The schematic representation of the research design is given in the **Figure 1 in Annexure**

Study population

The target group for this study will be adolescents studying 9th & 11th Classes in corporation schools with expected ages of 13-14 years and 16-17 years respectively.

Rationale for Choosing Corporation School:

This is a short pilot study and therefore, it is critical to work with Greater Chennai Corporation as the findings of the study will greatly influence policy and mental health program implementation by the city officials, Department of Education, Department of Women & Child development. While there are no clear studies done on variables such as vulnerability, existence of the social support system and availability and accessibility of professional mental health services, the project works on some key assumptions to target the Corporation schools as follows: Also, stigma perceived has not been formally studied in Chennai with this target group

1. Students from the Chennai Corporation School are vulnerable as their social support systems are weak, whereas students studying in the private schools have better social support system in place.
2. The lack of social support system itself creates fewer avenues for coping mechanism when compared to private school students. Parents of corporation school children have less awareness on depression.
3. Access to professional help (counseling support) is very much lacking due to poor socio-economic support.
4. Being the pilot project the target population will have homogeneity in terms of curriculum, exposure, management etc.

Rationale for Including 9th and 11th STD:

1. Academic pressure is high among the adolescent perusing 9th, 10th, 11th and 12th STD.
2. Due to Administrative reason, accessing 10th and 12th STD for an intervention is not possible, as they appear for the public examination at state level.
3. Non availability of students for continuous intervention. Since the project period is one year, the 10th STD students may change to higher secondary school and 12th STD may go for college studies after their exams.
4. 9th and 11th STD students will remain in the same school for pursuing next class. They can be followed in the subsequent years, assuming the intervention will be beneficial for coping their academic stress.

Sample size:

All the students of 9th and 11th standards in the selected schools are included for screening. Since the research is designed in such a way that all adolescents who found to be having sub clinical depression will be included for intervention irrespective of their allocation whether in control or intervention groups. However, to ensure the power of the study the required minimum sample size is calculated as follows:

Sample size calculation for intervention:

The minimum sample size is calculated based on the similar previous study conducted in Bihar (SEHER study)[23] using the formula:

World Vision

$$n = km$$

$$k = \frac{\left(z_{\frac{\alpha}{2}} + z_{\beta}\right)(2 * \sigma^2)}{(\mu_d)^2}\delta$$

Where

μ_d – mean difference to be detected between intervention groups

σ^2 - Variance of the cluster

m - Cluster size

δ - design effect

1 - β – Power

α - significant level

Cluster Design - Two groups - Unmatched studies - Comparison of means (Design Effect)

Mean Difference = 1.27, Standard Deviation = 4.8 (from the reference study)

Size of the cluster = 25, Design effect = 1.24, two sided

Power (%) = 80, Alpha Error (%) = 5

No. of clusters required = 11

Required minimum sample size = 278

Sampling technique:

Unit of randomization: School

Cluster randomization is the sampling technique in which the group as a whole is randomized (schools) and not the individual (adolescents) this technique is useful for group level intervention. One co-education school from each zone will be selected for pretest. There are 22 schools from 10 educational schools are coming out of our eligibility criteria (Higher secondary and coeducation schools). Out of 22 eligible schools in Chennai Corporation, 9 schools are chosen (one school from each educational zones, No schools from zone three as it didn't fall under our eligibility criteria) for screening by cluster randomization in which unit of randomization is schools. Total number of adolescents included in the study is **N= 1883 not exceeding 2000.** The sampling frame having the list of eligible schools are attached in annexure.

Selection of adolescent for intervention:

All adolescent who are at risk for sub clinical depression at the end of the screening exercises will be included for intervention.

Exclusion criteria:

Those who are already under psychological treatment or diagnosed to have clinical depression as per parent/care-giver / teachers information will be excluded for the intervention and further they will be referred to mental health facilities.
Adolescents who are not willing to participate/ Adolescents whose parents are not giving consent to participate in the study will not be included in the study.

Tools description

1. **Demographic Profile:**
   Socio demographic profile sheet includes the details such as age, sex, details about the parents, socio economic variables, and other personal details such as hobbies, interests, screen time, etc. (**Annexure 1**)
2. **Multi score Depression inventory for children (MDI-C)**[24] **:**
   MDI-C is a unique self-support inventory to assess the depression among children in the age group 12-17. It indicates how they feel and gives view on their emotional world. It has 79 true / false items on eight sub-domains including Anxiety, self-esteem, social introversion, instrumental helplessness, sad mood, pessimism, low energy and defiance. All the sub domains have separate score and the overall score for depression. Reliability of the tool is convincing with total Alpha score of 0.94, however the internal consistency across the subscales varies, out of 8 subscales 6 failed to meet the internal consistency of 0.70 (**Annexure 2**)

3. -**Child and adolescent Social Support scale (Version II)** [25,26]
   A reliable tool used to assess the perceived social support of children and adolescents in grades 3-12.This 60 item measure is divided into five subscales, which divide social support by network (parent, teacher, friend, classmate and school) The scale also analyses the types of support Emotional (love, trust, empathy)Informational (advice)Appraisal (offering evaluative feedback)Instrumental (Helping behaviour). Psychometric properties of this tool shows the reliability with alpha score ranging from 0.87-0.93 (**Annexure 3**)
4. **Students self-efficacy scale**[27]
   This scale contains 35 items divided into five dimensions such as Physical, Social, Emotional, Academic and Spiritual, for secondary, senior secondary school students of age group 13 to 18 years. The scale is presented as reliable with alpha score of 0.86. **(Annexure 4)**

Translation of the tools:

Once the tools are obtained, each tool will be reviewed and be translated in the regional language- Tamil. It will be done by the professional translator appointed by the MSSW project team. The Tamil versions will be translated back to English, as a joint exercise with World Vision team to ensure non-dilution of the tool content.

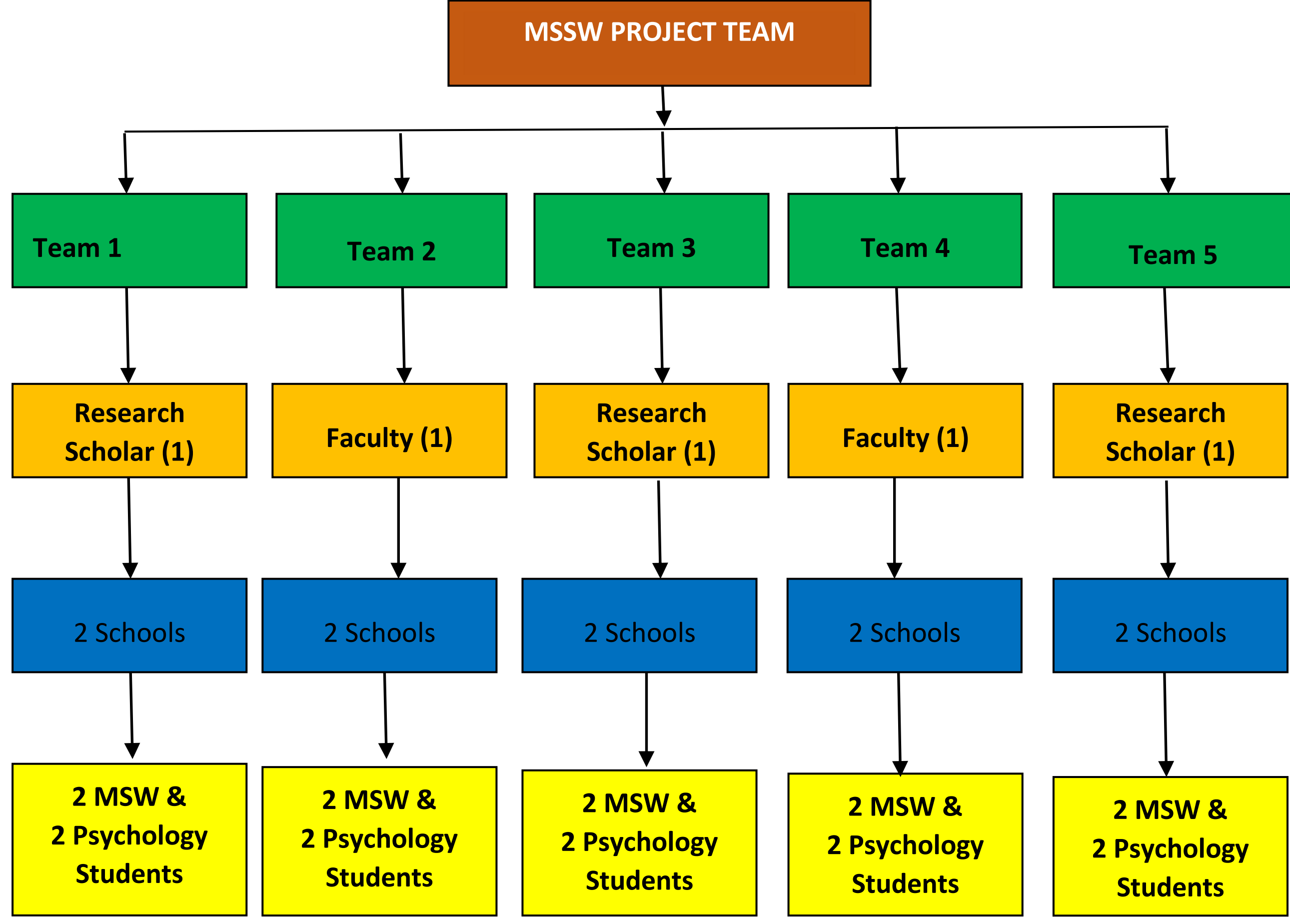
Field testing of the tools:

Split-Half Reliability will be established to check the internal consistency of the tool. The test will be administered to 200 adolescents of the same ages and classes who are not part of the study.

Adolescents identified as having the risk of sub clinical depression in these trial round will be provided with the same intervention, however they will not be included in the actual research. The implementation challenges in this trial will be addressed before beginning of the actual research.

Data collection plan:

Data collection team will consist of research Scholars and Post Graduate Students from Department of Social Work (Medical and Psychiatric Social Work) and from Department of Counselling Psychology. Each team will be monitored closely and the data quality will be cross verified systematically by the faculties in the research team. Both the social and the psychological aspects contributing to subclinical depression will be measure appropriately.
Enumerators will be trained in the tool administering procedure because it is important that the data collector follows the established procedures uniformly. Thus, data collectors will well trained for their tasks. The schematic representation of the data collection team is as follows:



Data entry and scoring of the screening tools:
Data will be entered by data entry operators in MS Excel and validation and scoring of the tools will be done by MSSW.
Data cleaning and analysis will be done by an independent statistician who are not involved with the data collection process.

1. Socio-demographic and other related variables will be summarized using mean (SD), median (IQR), frequencies and proportions.
2. Retention into care will be described cumulatively using proportions completing all the sessions of the intervention. Any adolescent who is continuously absent for more than three sessions of the intervention will be considered as drop out from the intervention.
3. Causal associations for sub clinical depression will be analysed using Chi square test with 0.95 Confidence Interval.
4. Risk analyses (Relative Risk) using logistic regression model. The associations will be inferred using B coefficient and 0.95 Confidence Interval.
5. Mixed effects regression with adjustment for clustering will be done to identify risk factors / independent predictors for change in depression score. The associations will be inferred using B coefficient and 0.95 Confidence Interval.

Variables with unadjusted p value <0.2 will be included in the regression models. The regressions models will be built using forward step wise method.

6. Appropriate tests of significance will be applied to assess the efficacy of the intervention which is tabulated as follows:

S.no	Purpose	Test of significance if the data is normally distributed	Test of significance if the data is non-normally distributed
1	Within group comparison (Pretest and post-test comparison)	The Paired sample T test	Wilcoxon signed-rank test
2	Relationship among variables	Karl Pearson correlation	Spearman rank-order correlation
3	Comparison among gender groups	Independent Samples t Test.	Mann-Whitney U test
4	Comparison between intervention and control group	Independent Samples t Test.	Mann-Whitney U test

	(Group A and Group B)		

Data Confidentiality:

Confidentiality will be maintained by keeping data collection and informed consent forms securely in a lockable cabinet and the electronic data file will be kept in a password protected computer accessible only by the research team. All the hard and soft copies of the data sets and consent forms will be submitted to World Vision after completion of the assignment and will be kept safely for five years after completion of research by WV. The enumerators and others involved in the evaluation refrain from discussing any of the information gathered with anyone other than those involved in the evaluation. Any identifiers will not be collected from the participants, details collected for communication purposes will be deleted/destroyed once the research is over.

Data ownership and use: All data collected during this OR will be the property of World Vision India and all raw data will be handed over to WV India on conclusion of the project to authorised point person. MSSW will have access to the data for future studies and reference, with due approval from WV India.

Ethical Considerations:

MSSW does not have a standing ERC therefore, the proposal will be submitted to ERC of WV India or other organization.

Ethical considerations will be followed during the execution of the study are:

For screening:

1. Administrative approval (No objection certificate) will be obtained from the educational commissioner of Chennai Corporation for the conduct of the research.
2. Informed consent will be obtained from the head of the school and parents of the adolescents during the orientation meeting with the parents before screening of adolescents. (**Annexure - 5)**

For Intervention:

3. For intervention for the adolescents who are at risk of having sub clinical depression, Written informed consent will be obtained from the parents/guardians of the adolescents and Assent from (Since the adolescents are under 18 years) will be got signed by the adolescents. All the forms will be administered in the local language (Tamil) and signed by the Parent/guardian/participant and the researcher. **(Annexure – 6 & 7)**

Reporting and Quality Assurance Mechanism:

Once in every month proceedings of research will be discussed internally among research team, Dean and Principal of the college and the key points will be sent to WVI.

Monthly progress report will be submitted to the World Vision India.

Expected Research Outcome:
Research questions addressed would include:

Pre intervention screening outcomes:

1. Prevalence of sub clinical depression among 13-17 years old adolescents in Chennai
2. Socio demographic determinants/ Predictors of sub clinical depression among 13-17 years old adolescents in Chennai

Post intervention screening outcomes:

1. To what extent can the intervention (IPT-AST) reduce sub clinical depressive symptoms among adolescents 13-17 years old in Chennai India?
2. To what extent can IPT-AST improve adolescent self-efficacy?
3. To what extent is the social support experienced by adolescents?
4. To what extent the increase in self-efficacy and social support would contributed to the reduction in depression?
5. Is IPT-AST equally as effective for boys and girls?
6. Implementation Science: What worked and didn't work in IPT-AST adaptation and implementation?

Over all Outcome of the study:

Outcome 1: Reduce depressive symptoms among adolescents 13-17 years old in Chennai India.

Outcome 2: Improve overall functioning among adolescents 13-17 years old in Chennai India.

Outcome 3: Improve social support of the 13-17 year old adolescents in Chennai, India

Limitations:

1. Schools with different board of studies like CBSC and ICSC are not part of the study. Thus the comparative risk analysis of different board of studies contributing to sub clinical depression will not be studied.
2. Private schools are not part of the study. Thus the comparison among educational stress between private and government schools contributing to sub clinical depression will not be studied.
3. Early and late adolescents are not part of the study. Thus the age related factors for sub clinical depression will not be studied.

Authority and Responsibility

a. **Tasks of the WV staff :**

- Getting permission from the schools both Chennai Corporation and permission from health department.

- Getting Ethics clearance from WVI ethics review board
- Intervention phase
- Analysis at different levels of research
- Final report writing based on results

b. Role of MSSW research assistants

- Pre and post screening using selected tools and scoring
- Data entry and scoring of the tools
- Report writing
- Assistance in dissemination of results

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List of annexures:

Screening tools

Consent forms

Assent form

List of eligible schools (Sampling frame)

Theory of Change

PAN

Copy of cancelled cheque

CVs of the point persons