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# BMJ Open Effectiveness of a government-led, multiarm intervention on early childhood development and caregiver mental health: a study protocol for a factorial cluster-randomised trial in rural China

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## ABSTRACT

**Introduction** The high incidences of both the developmental delay among young children and the mental health problems of their caregivers are major threats to *public health* in low-income and middle-income countries. Parental training interventions during early childhood have been shown to benefit early development, yet evidence on strategies to promote caregiver mental health remains limited. In addition, evidence on the optimal design of scalable interventions that integrate early child development and maternal mental health components is scarce.

**Methods and analysis** We design a single-blind, factorial, cluster-randomised controlled, superiority trial that will be delivered and supervised by local agents of the All China Women's Federation (ACWF), the nationwide, government-sponsored social protection organisation that aims to safeguard the rights and interests of women and children. We randomise 125 villages in rural China into four arms: (1) a parenting stimulation arm; (2) a caregiver mental health arm; (3) a combined parenting stimulation and caregiver mental health arm and (4) a pure control arm. Caregivers and their children (aged 6–24 months at the time of baseline data collection) are selected and invited to participate in the 12-month-long study. The parenting stimulation intervention consists of weekly, one-on-one training sessions that follow a loose adaptation of the Reach Up and Learn curriculum. The caregiver mental health intervention is comprised of fortnightly group activities based on an adaptation of the Thinking Healthy curriculum from the WHO. Primary outcomes include measures of child development and caregiver mental health. Secondary outcomes include a comprehensive set of physical, psychological and behavioural outcomes. This protocol describes the design and evaluation plan for this programme.

**Ethics and dissemination** This study received approval from the Institutional Review Board of Stanford University (IRB Protocol #63680) and the Institutional Review Board of the Southwestern University of Finance and Economics

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The present study uses factorial design to decompose the integrated effects of a parental training intervention and a caregiver mental health intervention.
- ⇒ By working closely with local government bodies to hire community members as this programme's delivery agents, this study provides evidence of the impact of interventions delivered by the government on a relatively large scale.
- ⇒ For the first time, our comprehensive adaptation of an internationally recognised mental health curriculum to the Chinese rural context can be used by other research practitioners and groups throughout China.
- ⇒ The rapid urbanisation in China could lead to potential attrition of a substantial portion of the sample due to rural-to-urban migration.

in Chengdu, Sichuan, China. Informed oral consent will be obtained from all caregivers for their own and their child's participation in the study. The full protocol will be publicly available in an open-access format. The study findings will be published in economics, medical and public health journals, as well as Chinese or English policy briefs.

**Trial registration number** AEA RCT Registry (AEARCTR-0010078) and ISRCTN registry (ISRCTN84864201).

## INTRODUCTION

### Background

Up to 250 million children under 5 years in low- and middle-income countries (LMICs), accounting for 43% of the young children living in those countries, are estimated to be at risk of missing out on their developmental potential.<sup>1</sup> The brain develops most rapidly

during the critical window between birth and age 3, which is foundational for future health, well-being and skill formation. Delayed attainment of age-specific developmental milestones during this early stage of childhood has been associated with lifelong limitations in a wide range of outcomes that include academic achievement, adult earnings and physical well-being.<sup>2-4</sup> In response to these concerns, an increasing number of early childhood development (ECD) projects has been implemented in a number of LMICs since 2010.<sup>5</sup> As a result, a large, rapidly expanding body of empirical research now shows that ECD programmes focusing on caregiver-child interaction can elevate caregiver engagement in stimulating parenting practices and, as a result, benefit ECD outcomes.<sup>6,7</sup>

In addition to the high prevalence of ECD delays, maternal mental health problems are common in LMICs. Up to one in four women living in LMICs experiences depressive symptoms during pregnancy or the first year postpartum (ie, the perinatal period), yet over 90% lacks access to any type of social support or mental health services.<sup>8</sup> Evidence suggests that maternal mental health problems are associated with reduced engagement in stimulating parenting practices, an essential element to help children reach their developmental milestones.<sup>9-11</sup> Furthermore, studies have established a link between poor maternal mental health and low cognitive, language, social and emotional development during early childhood.<sup>9,10,12</sup> In comparison to ECD programmes, few interventions for maternal mental health promotion have been implemented in LMICs. The Thinking Healthy Programme (THP) is one of the very few evidence-based programmes (originally developed for use in Pakistan and India) that has been designed to reduce perinatal depression through modified cognitive-behavioural therapy.<sup>13</sup> It was later recommended by the WHO for global dissemination. Since then, adapted versions of the curriculum have been implemented in a number of other LMICs such as Bangladesh, Vietnam and Peru.<sup>14-17</sup> Despite the promising progress, scaling the THP in under-resourced areas remains a major challenge.<sup>18</sup> Additionally, because mental health is highly culturally sensitive, more studies are needed to understand the cultural compatibility of the THP in a wider range of diverse cultural contexts.<sup>19</sup>

Despite the rich literature calling for the integration of ECD and maternal mental health intervention components due to the potential synergies in delivery and programme effects,<sup>6,20,21</sup> evidence is both limited and mixed in terms of how and to what extent integrated interventions can have effects on child development and maternal mental health. For the limited number of earlier interventions with both ECD and caregiver mental health components, each finds significant improvements in child development. However, only a subset finds evidence of significant protective effects on maternal depressive symptoms, while others detect no impact on maternal depression outcomes.<sup>22-24</sup> Two separate trials integrated the THP into child health and development interventions<sup>15,25</sup>; however, since those trials used parallel

designs, where all treatment arms had both a mental health component and child health and ECD components, it remains unclear whether integrated mental health components can significantly improve either ECD or caregiver mental health outcomes. Therefore, a factorial design trial is needed to decompose the integrated effects of ECD and caregiver mental health interventions.

Even when an intervention programme has been proven effective in a certain context, improving the scalability and sustainability of this intervention programme is yet another challenge.<sup>26</sup> Considering that public programmes often face the most stringent resource constraints in the areas that are most in need of such services, the literature has suggested to integrate new programmes into existing public service systems that are present even in the most disadvantaged areas, in order to improve inclusiveness of the disadvantaged populations.<sup>27-29</sup> Many existing programmes rely on community health workers (CHWs) for programme delivery, which puts CHWs in the spotlight as a critical frontline resource for public service delivery in underdeveloped areas.<sup>29</sup> However, emerging evidence suggests that CHWs are often overburdened with their workload, which may constrain programme sustainability.<sup>30</sup> For example, the THP was originally designed for delivery by CHWs, but the programme was later adapted to be delivered by housewives because of implementation challenges due to the excessive workload requirements for CHWs, especially in resource-poor areas.<sup>31</sup> The Lancet Series on *Advancing ECD* suggested the possibilities of implementing ECD interventions through child and social protection services<sup>29</sup>; however, due to a lack of CHWs with a sufficiently high educational background, it remains unclear whether this channel can be effective.

To address these challenges, we developed a factorial, cluster-randomised controlled trial that integrates a previously field-tested ECD intervention (one that follows a loosely adapted version of the *Reach Up and Learn* curriculum) with a caregiver mental health intervention (that follows a loosely adapted version of the THP curriculum). Both of the interventions are delivered and supervised by local agents of the All China Women's Federation (ACWF), the nationwide, government-sponsored social protection organisation that aims to safeguard the rights and interests of women and children in mainland China.<sup>32</sup> The ACWF has the ability to reach households in remote areas and bring the programme to a large, even nationwide scale, mainly because of two reasons. First, in line with China's political administrative divisions, the ACWF has national, provincial, prefectural (ie, at the level of prefectural cities), county-level, township-level and village-level administrative infrastructures. Second, the ACWF plays an important role in the transmission and implementation of state policy and represents the interests of women and children to the state, making it a promising agency to advocate for effective programmes via policy recommendations. Nevertheless, no study until now

has examined the ACWF's ability to effectively deliver maternal and child health interventions.

### Study objectives

We aim to evaluate the effectiveness of a factorial, cluster-randomised controlled trial testing the impacts of parental training focusing on child psychosocial stimulation and caregiver mental health support on child development and caregiver mental health outcomes. The current study has three specific objectives: (1) to examine whether the parental training intervention has a significant effect on child development outcomes and caregiver depressive symptoms as compared with the control arm, which receives no services except for the limited standard-of-care services that are available to rural Chinese villagers; (2) to examine whether the mental health intervention has a significant effect on child development and caregiver depressive symptoms as compared with the control arm and (3) to examine whether combining these two interventions has a significant effect on child development and caregiver depressive symptoms as compared with the control arm. This study is one of the first studies to employ a factorial design to understand how each component of such combined interventions can affect child development and caregiver mental health outcomes, directly or via synergies between programme components.

### METHODS AND ANALYSES

This protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines (see online supplemental appendix 1).

#### Study design

The study design is a 12-month, single-blind, factorial, cluster-randomised controlled, superiority trial, in which 125 villages were randomly allocated to one out of four arms (see figure 1): (1) a parental training intervention focusing on child psychosocial stimulation, (2) a caregiver mental health promotion intervention, (3) a combined intervention of both parental training and caregiver mental health promotion interventions and (4) a pure control arm that does not receive any intervention. The randomisation was executed at the village level on a 1:1:1:2 allocation ratio (ie, with the control arm being

twice the size of an intervention arm). The study enrolled children aged 6–24 months at the time of baseline survey and their caregivers. The baseline survey was only given to the primary caregivers due to limitations to the survey administration capacity, but the endline survey after 12 months of intervention has been completed and will be administered to each of the primary and secondary caregivers.

The parenting intervention consists of weekly one-on-one training sessions based on a scripted curriculum that was loosely adapted from *Reach Up and Learn* curriculum.<sup>33</sup> The mental health intervention consists of fortnightly group sessions and uses a curriculum adapted from both the THP and its sister curriculum, the *Thinking Healthy Peer-Delivered Programme Plus* (THPP+).<sup>14,34</sup> In order to improve the sustainability of the intervention, the intervention components are delivered by local ACWF agents in each village. They are monitored and supervised by ACWF agents at the county and city levels. The research team provides onboarding training to ACWF agents at the beginning of the intervention and in-time technical support during the implementation of the intervention.

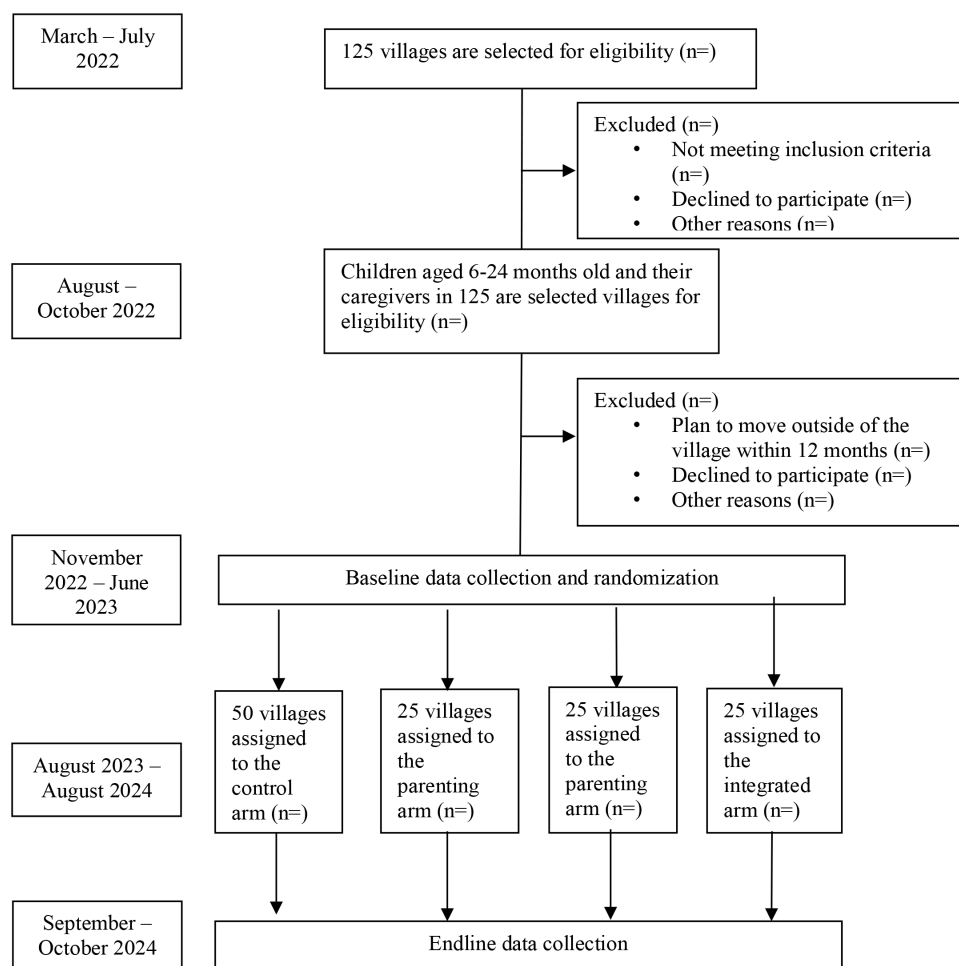
#### Study setting and enrolment

The study will take place in 125 rural villages in Ya'an, a prefecture in Sichuan province. Ya'an is the tenth largest prefecture in Sichuan<sup>35</sup> and has experienced substantial urbanisation in its central, prefectural city over the last decade.<sup>35–37</sup> With regard to child development and caregiver mental health outcomes in the study area, evidence from rural Ya'an has yet to be collected and analysed to establish a baseline. However, previous literature has found that in rural areas of China, around 45% of children under the age of 3 years are cognitively, linguistically or social-emotionally delayed.<sup>7</sup> Concurrently, up to 40% of caregivers in rural China display symptoms of at least one common mental health disorder, such as depression, anxiety or stress.<sup>10</sup>

Ya'an consists of eight counties, from which we exclude two counties that are located in mountainous areas and have low population densities. In the remaining six counties, study villages are selected based on the following inclusion criteria: (1) the village is located outside of minority townships (ie, townships where the majority of the population belong to a non-Han ethnic minority);

		Caregiver mental health promotion component	
		Treatment	Control
Parental training component	Treatment	25 villages	25 villages
	Control	25 villages	50 villages

**Figure 1** The factorial design of the trial.



**Figure 2** Trial flow diagram.

(2) the village has a population of at least 1000 inhabitants; (3) the village receives infrastructure support from the local village committee to establish a child centre (ie, the available space at a central location in the community where the intervention will take place) and (4) at least one village-affiliated ACWF agent who is willing to participate in the study is present in the village. Based on these criteria, we randomly select 125 rural villages from the pool of eligible villages. To avoid spillover effects between villages, we replace neighbouring villages in the sample with other randomly selected villages from the list of eligible villages. Each of the villages included in the final sample is located at a distance of at least 5 km away from the nearest other village in the sample.

### Eligibility criteria and recruitment strategy

#### Participant recruitment

The trial flow chart (figure 2) shows the process and timeline of participant recruitment and evaluation. The target population for the present study consists of children aged 6–24 months old at the time of baseline survey administration and their caregivers (ie, primarily mothers and grandmothers of the children). All age-eligible children in each village and their caregivers, regardless of how many live in the village, will be invited to participate in

the study as long as they do not plan to move outside of the selected villages during the study period. Based on a previous study conducted in rural China,<sup>38</sup> the number of the eligible households within each rural village often varies, yet primarily ranges from 8 to 15 households. The parenting stimulation intervention will be open to both female and male caregivers of children. Since the mental health curriculum is designed for female caregivers (who consist of almost all the caregivers of young children in rural China), we will only invite primary and secondary caregivers if they are female to participate in the group sessions.

#### CWW recruitment

We label the intervention delivery agents as ‘community women workers’ (henceforth abbreviated as CWW), who is an ACWF affiliate working at the village level. Depending on the number of children and treatment arms in each village, one or two CWWs will be selected through an interview process by both the research team and an upper-level ACWF committee. Specifically, one CWW will be selected for each the parental training arm and the caregiver mental health arm unless more than 20 households are enrolled in the study. If the number of enrolled households exceeds 20, we would seek advice



from local ACWF affiliate in the village on whether a second CWW is needed to sufficiently deliver intervention. If so, we would select and hire a second CWW for the village. Inclusion criteria for CWWs are (1) middle school educational attainment or above and (2) being a long-term village resident without plans to migrate away from the study village during the study period.

To improve the sustainability of the study, CWWs will be employed by the city-level ACWF based on their monthly workload. In addition to training CWWs, the study team will train county-level and city-level ACWF affiliates to supervise CWWs. During the intervention, county-level ACWF affiliates will conduct monthly check-ins with CWWs under the support of the study team to identify and troubleshoot challenges in intervention implementation. A wide range of monitoring data will be collected on the frequency and timing of parenting and mental health sessions via a tablet application that is designed to facilitate the monitoring and management of the intervention implementation. In terms of CWWs who are unable to execute the intervention tasks (see online supplemental appendix 2 for the specification), members of the county-level ACWF will conduct in-person observations and identify areas for improvement, and the study team will provide enhancement trainings to the specific CWWs if needed.

## Intervention

### Parenting intervention

For each village assigned to the parenting or the integrated intervention arm, we will install a child centre in an existing space at a central location in the community provided by a local village committee. The research team will provide all child centres with child-friendly decorations, an open area for one-on-one parenting sessions as well as toys and books that are required for use during the parenting sessions. Child centres will be operated by one or two CWWs, who deliver one-on-one parenting training sessions following a scripted curriculum called the *Parenting the Future* curriculum.

The *Parenting the Future* curriculum was adapted from the *Reach Up and Learn* curriculum.<sup>33 39 40</sup> Local ECD experts from China adapted the curriculum to fit the context of rural China. Weekly stage-based, age-appropriate sessions were developed targeted at children between 6 and 36 months of age. Each weekly session contains modules focusing on two out of four developmental modules: cognition, language, motor and social-emotional skill development. At the end of each session, the CWW encourages caregivers to take toys and books home and to practice the activities at home as frequently as possible between two sessions. The *Parenting the Future* curriculum has been field tested and demonstrated effective at improving cognitive development of young children in multiple randomised controlled trials across China.<sup>38 41 42</sup>

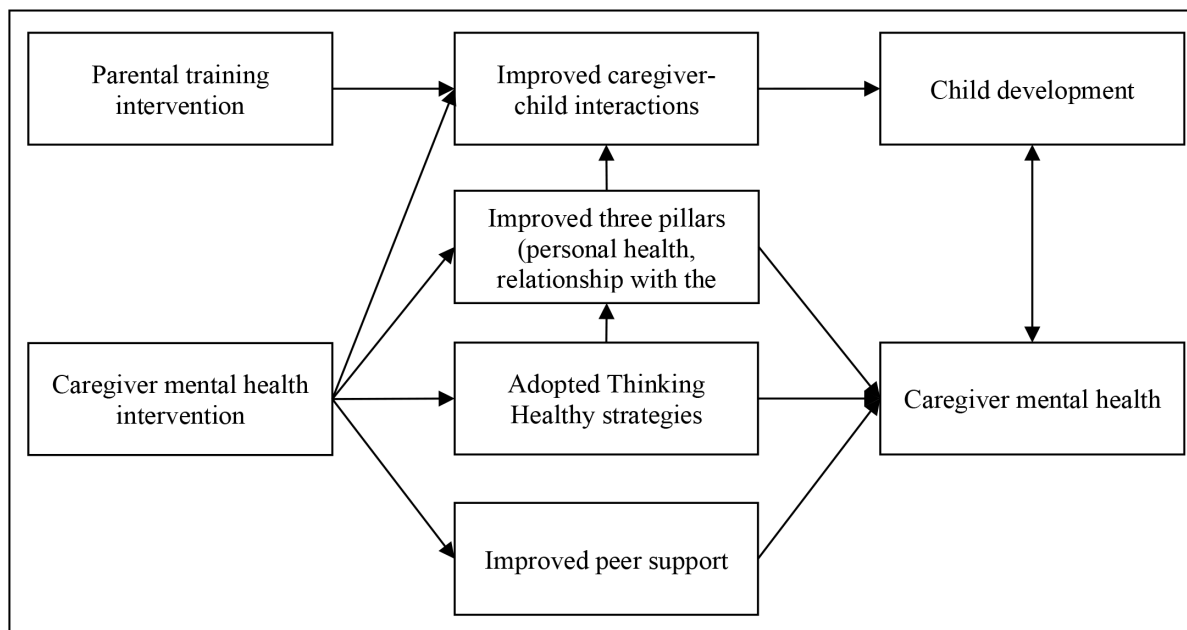
This study will employ a hybrid delivery strategy where caregiver-child dyads can attend weekly training sessions

either at child centres (centre-based format) or in their homes (home-visitation format). Compared with the home-visitation format, the center-based format is considered less labour intensive and more efficient, as it reduces the costs of commuting for CWWs. However, previous literature suggests that the effect of centre-based parenting interventions on child development can diminish due to lower compliance rates among the most disadvantaged children with relatively poor cognitive development at baseline.<sup>38</sup> Therefore, to promote compliance to the parenting intervention while keeping labour costs low, CWWs encourage caregivers to attend the weekly sessions at the child centre. However, if caregivers cannot or choose not to come to the child centre, CWWs will schedule home visits and deliver the sessions at the caregiver's homes.

### Mental health intervention

The mental health intervention, called Thinking Healthy Extended Programme (THEP), consists of 24 group sessions delivered once every 2 weeks. The THEP was developed by the research team and is based on both the THP<sup>14</sup> and a series curricula of the THP named THPP+.<sup>34</sup> The THP is an evidence-based psychosocial intervention designed to reduce perinatal (ie, the period from pregnancy to 10 months after childbirth) depressive symptoms through modified cognitive-behavioural therapy (CBT). As a significant part of the WHO's flagship mental health gap action programme (the mhGAP), the THP programme has been shown to be effective in reducing depressive symptoms and has since been implemented in a number of LMICs.<sup>15 16 43</sup> However, since THP targets the perinatal period, much of its content is not compatible with caregivers of children aged 6–36 months old. THPP+, on the other hand, was developed by the same research team and aims to provide continued mental health support beyond the perinatal period. Although the THPP+ has been designed for caregivers of children in the same age range as the children targeted in the current intervention, no evidence of significant treatment impacts of the THPP+ on maternal depression was detected in earlier studies, possibly due to lack of modified CBT techniques, low intensity and being delivered by lay community workers.<sup>34</sup> Therefore, instead of directly translating and adapting the THP or THPP+, the THEP combines the THP and THPP+ and integrates essential principles, elements and activities from both curricula to develop a unique curriculum system.

The THEP was designed to be a low-intensity intervention, meaning the THEP has been modified for use with fewer resources than conventional psychological treatments by specialists such that the intervention is feasible also in less-resourced communities.<sup>14</sup> Each session of the THEP has a specific theme focusing on caregivers' personal health, caregiver-child relationship or caregivers' relationships with close family members and friends (ie, these are the three pillars of the curriculum). The structured group activities consist of discussions and games to



**Figure 3** Intervention mechanisms.

help caregivers learn and apply simplified CBT strategies, adopt healthy practices in daily activities, share personal experiences of childrearing and gain peer support.

The THEP also has unique features that differentiate itself from the THP and THPP+. First, THEP was designed for both mothers and grandmother caregivers with a view to the universal phenomenon of intergenerational parenting in China.<sup>44</sup> We assign mothers and grandmothers to separate groups in light of their differences in childrearing practices and experiences.<sup>9 45</sup> Second, the THEP is a universal intervention that includes women regardless of their baseline mental health status, meaning that we do not screen caregivers for any mental health symptoms to determine the eligibility for the mental health intervention. A wide range of literature indicates that stigma in mental health is especially widespread in Asia and underdeveloped areas.<sup>46 47</sup> Screening for mental health symptoms at the community level may increase the risk of discrimination against caregivers with mental health problems. Therefore, the THEP was designed to be a preventative intervention for mental health symptoms, and caregivers who may be experiencing severe symptoms will be referred for additional treatment. Finally, the content of the THEP was carefully adapted to fit the cultural context of rural China. The mechanisms of both parenting stimulation and caregiver mental health interventions are shown in [figure 3](#).

### Outcome measures

The effectiveness of the intervention will be evaluated on a range of child and caregiver outcomes. The primary and secondary outcomes will be measured at the time of baseline and endline data collection. Both surveys will be administered by trained enumerators. The details of the outcome measures are shown in [table 1](#). In addition to

the two surveys, the comprehensive administrative data will be collected automatically by a tablet application.

### Primary outcomes

The primary outcomes are a list of measures of child development and caregiver mental health outcomes. Child development is measured using the Bayley Scales of Infant and Toddler Development, third edition (Bayley-III)<sup>48</sup>; the short version of the Caregiver-Reported Early Development Index (CREDI)<sup>49</sup>; the Brief Infant-Toddler Social and Emotional Assessment (BITSEA)<sup>50</sup>; and Wolke Social-Emotional Behaviour Ratings. Child development is assessed using the standardised test scores each child receives. In addition, the proportion of the children whose score falls below a prespecified test-specific cut-off score is used to quantify the prevalence of developmental delay.

Caregiver mental health is measured using the eight-item version of the Patient Health Questionnaire (PHQ-8) and the 21-item version of the Depression Anxiety Stress Scale (DASS-21).<sup>51 52</sup> Caregiver mental health is assessed using the continuous scores. In addition, the prevalence of the symptoms of mental health problems (eg, symptoms of depression, anxiety and stress) at both mild and severe levels is assessed using the cut-off scores provided by each scale.

### Secondary outcomes

The secondary outcomes consist of a combination of physical, psychological and behavioural outcomes that can mediate the intervention effects on the primary outcomes of interest. The secondary outcomes include the following measures:

- ▶ Child anthropometric growth outcomes and health-related behaviours: Child anthropometric

**Table 1** Description of the measurements

Primary outcomes	Measurements	Description
Child cognitive, language, motor and social-emotional development	Bayley-III	Trained enumerator administers the assessment at the child's home. Validated and widely used in China. <sup>7 62</sup>
	CREDI-SF	20 items assessing the overall development of a child. The long form has been validated in China but not this short form. <sup>63</sup> Use as a supplement of Bayley-III.
	BITSEA	42 items assessing child social-emotional development. Validated in China. <sup>64</sup>
	Wolke Social-Emotional Behaviour Ratings	6 items assessing child social-emotional development. Rated by the Bayley-III enumerators based on the interaction with the children during the Bayley-III testing process. Not validated in China but has been used in a wide range of LMICs. <sup>65</sup>
Caregiver depressive, anxiety and stress symptoms	PHQ-8	8 items assessing depressive symptoms; validated in China and other LMICs. <sup>66</sup>
	DASS-21	21 items assessing depression, anxiety and stress symptoms; commonly used in rural China. <sup>67 68</sup>
Secondary outcomes	Measurements	Description
Child growth	Anthropometric measurements	Trained enumerators follow the standard protocols for anthropometric measurements.
Child screen-use time	Self-made items	7 items adapted from Zhao <i>et al</i> assessing the time children spent on electronic devices and video programmes. <sup>69</sup> Not validated in China.
Child sleep habit	BISQ - R SF	19 items assessing child sleep patterns. Validated in China. <sup>70</sup>
Stimulating parenting practices	FCI	21 items assessing parental stimulation at home. Widely used but not validated in China. <sup>7</sup>
	HOME	8 observation-based items. Widely used and validated in China. <sup>71</sup>
Caregiver health	Self-made items	13 items adapted from China Health and Retirement Longitudinal Survey (CHARLS). <sup>72</sup>
Caregiver's perceived relationship with child	MORS-SF	14 items assessing caregiver's perception of caregiver-child bonding. Validated in LMICs. <sup>73</sup>
Caregiver perceived social support	MSPSS	12 items assessing the perceived adequacy of social support from family, friends and significant others. Validated in China. <sup>74</sup>
Parenting stress	PSI-SF	36 items assessing parental distress, parent-child dysfunctional interaction and difficult child. Validated in China. <sup>75</sup>
Parenting self-efficacy	TOPSE	48 items assessing eight domains of parenting efficacy perceived by caregiver. Validated in China. <sup>76</sup>
Parenting daily hassles	PDH	20 items assessing the frequency and intensity of potential parenting hassles experienced by caregiver. Not validated in China.
Caregiver mental health literacy	MHLS	35 items assessing the understanding of mental health among caregivers. Validated in China. <sup>77</sup>
<p>Bayley-III, Bayley Scales of Infant and Toddler Development-III; BISQ-R SF, Brief Infant Sleep Questionnaire Short Form; BITSEA, Brief Infant-Toddler Social and Emotional Assessment; CREDI-SF, Caregiver Reported Early Development Instruments; DASS, Depression, Anxiety, and Stress Scales; FCI, Family Care Indicator; HOME, Home Observation for Measurement of the Environment; MHLS, Mental Health Literacy Scale; MORS-SF, The Mothers' Object Relations Scale short form; MSPSS, Multidimensional Scale of Perceived Social Support; PDH, Parenting Daily Hassle; PHQ-8, Patient Health Questionnaire-8; PSI-SF, Parenting Stress Index-Short Form; TOPSE, Tool to Measure Parenting Self-Efficacy.</p>		



measurements, child screen-time use measured by self-made items and child sleep habit measured by the revised short form of Brief Infant Sleep Questionnaire (BISQ-R SF).<sup>53</sup>

- ▶ Stimulating parenting practices: Based on both self-reported and enumerator observed measures. The self-reported measurement include the Family Care Indicators (FCI),<sup>54</sup> and the enumerator observed measurement uses the Home Observation Measurements of the Environment (HOME).<sup>55</sup>
- ▶ Three pillars of THEP sessions: Caregiver physical health measured by self-made items; caregiver relationship with their children measured with the short form of the Mother's Object Relations Score (MORS-SF)<sup>56</sup>; and caregiver relationships with close family members and friends measured by Multidimensional Scale of Perceived Social Support (MSPSS).<sup>57</sup>
- ▶ Parenting perceptions: Parenting stress measured by the short form of Parenting Stress Index (PSI-SF),<sup>58</sup> parenting efficacy measured by the Tool to Measure Parenting Self-efficacy (TOPSE)<sup>59</sup> and parenting daily hassles measured by the Parenting Daily Hassle Scale (PDH).<sup>60</sup>
- ▶ Caregiver mental health literacy: Measured by the Mental Health Literacy Scale (MHLS).<sup>61</sup>

#### Administrative records

The tablet application collects administrative data on parenting and mental health sessions, including the date, time and location of each session, along with the participants' relationship with their children. For the parenting intervention, the tablet application also tracks records of each toy and book the household borrows from the child centres.

#### Masking

Households in the control arm are not informed about the intervention programmes and are only invited to participate in the baseline and endline surveys. Child development status, caregiver mental health status and all other information that could be derived from the baseline and endline surveys are masked for all households. However, due to ethical considerations, children whose development level is 2 SD below the mean of the norm population and caregivers who show severe depressive symptoms or suicidal ideation will be immediately referred to medical evaluation. The survey enumerators are separately recruited before each of the rounds of baseline and endline data collection. Because enumerators work with CWWs to survey households and because caregivers in the treatment arms can be easily identified by enumerators during the interviews, masking of treatment conditions to enumerators at endline data collection is unnecessary. However, enumerators were blinded to treatment allocation. The CWW trainings for delivering parenting and mental health interventions are conducted separately, and the training of CWWs does not inform the existence

of the other intervention arms. The treatment allocation is not necessarily masked to CWWs for two reasons: (1) CWWs from different treatment arms are all supervised by the county-level ACWF affiliates and (2) CWWs are ACWF affiliated; therefore, communications might take place outside of the intervention implementation. CWWs are instructed only on curriculum delivery and are blinded to the trial design and assessment procedures. Data analysts are blinded to the identification of the study arms.

#### Power calculation

Power calculations are estimated assuming two-tailed tests and a 5% significance level for the following three indicators: child cognitive development, stimulating parenting practices and caregiver depressive symptoms. Based on previous field research, we assume that, on average, ten eligible households will be present in each village. The intracluster correlation (ICC) of each outcome is assumed to be 0.01. In our factorial design, we randomly assign 25 villages to each treatment arm and double the size of the control arm to 50 villages (with a view to the significant cost of intervention implementation). Based on a meta-analysis conducted in rural China, we assume the minimal detectable effect size (MDE) of each of the treatment arms on child cognitive development and stimulative parenting practices to be 0.26 SD and 0.39 SD, respectively.<sup>7</sup> Using these parameters, the results of the power calculation show that the current study has, respectively, 88% and 99% statistical power to detect an impact on child cognitive development and stimulating parenting practices between each treatment arm and the control arm. For the mental health intervention, however, due to a lack of earlier comparable studies, the MDE on caregiver depressive symptoms remains unclear. However, we can calculate that the study design allows to detect a MDE of 0.23 SD (or larger) on caregiver mental health outcomes with at least 80% statistical power.

#### Statistical analysis

The quantitative analysis will be conducted using STATA (V.18) following the CONSORT guidelines. We will create a flow chart that will include the number of participants at each stage of the trial, including the number of participants that are eligible, enrolled, randomised, attrited and analysed regarding the primary outcomes. The initial analyses consist of unadjusted comparisons between the control arm and treatment arms on both primary and secondary outcomes. Means and SDs will be reported for continuous outcomes; numbers and proportions will be reported for categorical outcomes. Differences will be considered statistically significant if the *p* value of the hypothesis test is less than 0.05.

The primary analysis is an intention-to-treat (ITT) analysis adjusted for the baseline measurements of the outcomes, baseline controls and county stratum fixed effects. Analyses of impacts on continuous outcomes

will use ordinary least squares (OLS) regressions; and analyses of impacts on binary outcomes will use logistic regression models. Standard errors are clustered at the village level using the cluster-corrected Huber-White estimator. We also estimate the per-protocol effects of each arm on the outcomes of participants with relatively high compliance rate. Effect sizes will be reported as standardised mean differences for continuous outcomes and adjusted risk ratios for binary outcomes, both at 95% significant levels.

The secondary analysis aims to examine heterogeneity in treatment effects across caregiver and child subgroups. We conduct this analysis by adding each of the subgroup indicators and the interaction term between the treatment assignment indicator and the subgroup indicator to the ITT regression models from the primary analysis specified above. We prespecify the following subgroups of interest for the subgroup heterogeneity analysis:

- ▶ Child sex (male or female).
- ▶ Socioeconomical status (SES) of households at baseline defined by family asset index scores. SES will be analysed using continuous scores as well as categories defined based on quartile scores.
- ▶ Baseline development of the children as measured with Bayley-III test scores in the domains of cognitive, language and motor development and Wolke scores in the domain of social-emotional development. The developmental level will be analysed using continuous scores as well as categories defined based on quartile scores.
- ▶ Relationship between the children and their primary caregivers at baseline, which will be classified as mothers, grandmothers and others.
- ▶ Type of parental migration at baseline, which will be classified as non-migration, father migration, mother migration and father-mother migration.

### Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination plans of our study.

## ETHICS AND DISSEMINATION

### Research ethics approval

This study received approval from the Institutional Review Board of Stanford University (IRB Protocol #63680) and the Institutional Review Board of the Southwestern University of Finance and Economics in China.

### Protocol amendments

Protocol modifications will be fully disclosed in future publications. In case of any changes, the protocol in the clinical registry and IRBs will be updated accordingly.

### Informed consent

All caregivers must give informed oral consent for their own and their children's participation in the study.

Enumerators trained in the informed consent process will explain the study risks and benefits, answer any questions and gather informed oral consent. We do not collect written consent as many rural caregivers in China, particularly grandmothers, are illiterate. Online supplemental appendix 3 provides a model consent form.

### Confidentiality

Only the field investigators and the project coordinators have access to personal data for intervention implementation before and during the trial. Deidentified data are available to the research team or other scientists under a cooperation agreement. All data are password-protected at all stages. No participant's identity will be shared in any format to protect confidentiality.

### Declaration of interests

We declare no financial or other competing interests for principal investigators for the overall trial and each one of the study sites.

### Dissemination policy

The full protocol will be publicly available in an open-access format. The study findings will be published in economics, medical and public health journals. The study findings will also be disseminated to all stakeholders beyond academia through policy briefs to the government and fact sheets with plain language to the communities and households. Only researchers and investigators who meet ICMJE criteria for authorship will be included as co-authors. Other contributors, such as enumerators, CWWs, or participants, will be acknowledged in the published manuscripts.

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## REFERENCES

- Lu C, Black MM, Richter LM. Risk of poor development in young children in low-income and middle-income countries: an estimation and analysis at the global, regional, and country level. *Lancet Glob Health* 2016;4:e916–22.
- Gertler P, Heckman J, Pinto R, et al. Labor market returns to an early childhood stimulation intervention in Jamaica. *Science* 2014;344:998–1001.
- Heckman JJ, Moon SH, Pinto R, et al. The rate of return to the Highscope Perry preschool program. *J Public Econ* 2010;94:114–28.
- Knudsen EI, Heckman JJ, Cameron JL, et al. Economic, Neurobiological, and behavioral perspectives on building America's future workforce. *Proc Natl Acad Sci U S A* 2006;103:10155–62.
- Black MM, Walker SP, Fernald LCH, et al. Early childhood development coming of age: science through the life course. *The Lancet* 2017;389:77–90.
- Aboud FE, Yousafzai AK. Global health and development in early childhood. *Annu Rev Psychol* 2015;66:433–57.
- Emmers D, Jiang Q, Xue H, et al. Early childhood development and parental training interventions in rural China: a systematic review and meta-analysis. *BMJ Glob Health* 2021;6:e005578.
- Fisher J, Cabral de Mello M, Patel V, et al. Prevalence and determinants of common perinatal mental disorders in women in Low- and lower-middle-income countries: a systematic review. *Bull World Health Organ* 2012;90:139G–149G.
- Yue A, Gao J, Yang M, et al. Caregiver depression and early child development: A mixed-methods study from rural China. *Front Psychol* 2018;9:2500.
- Zhang S, Dang R, Yang N, et al. Effect of Caregiver's mental health on early childhood development across different rural communities in China. *Int J Environ Res Public Health* 2018;15:2341.
- Zhong J, Wang T, He Y, et al. Interrelationships of Caregiver mental health, parenting practices, and child development in rural China. *Children and Youth Services Review* 2021;121:105855.
- Gelaye B, Rondon MB, Araya R, et al. Epidemiology of maternal depression, risk factors, and child outcomes in low-income and middle-income countries. *Lancet Psychiatry* 2016;3:973–82.
- Rahman A, Malik A, Sikander S, et al. Cognitive behaviour therapy-based intervention by community health workers for mothers with depression and their infants in rural Pakistan: a cluster-randomised controlled trial. *Lancet* 2008;372:902–9.
- World Health Organization. Thinking healthy: a manual for Psychosocial management of perinatal depression, WHO generic field-trial version 1.0, 2015; 2015. World health organization
- Pitchik HO, Tofail F, Rahman M, et al. A Holistic approach to promoting early child development: a cluster randomised trial of a group-based, Multicomponent intervention in rural Bangladesh. *BMJ Glob Health* 2021;6:e004307.
- Eappen BS, Aguilar M, Ramos K, et al. Preparing to launch the 'thinking healthy programme' perinatal depression intervention in urban Lima, Peru: experiences from the field. *Glob Ment Health (Camb)* 2018;5:e41.
- Nisar A, Yin J, Yiping N, et al. Making therapies culturally relevant: translation, cultural adaptation and field-testing of the thinking healthy programme for perinatal depression in China. *BMC Pregnancy Childbirth* 2020;20:368.
- Patel V, Chowdhary N, Rahman A, et al. Improving access to psychological treatments: lessons from developing countries. *Behav Res Ther* 2011;49:523–8.
- Marsella AJ, Yamada AM. n.d. Culture and mental health. handbook of Multicultural mental health. *Elsevier*;2000:3–24.
- Rahman A, Surkan PJ, Cayetano CE, et al. Grand challenges: integrating maternal mental health into maternal and child health programmes. *PLoS Med* 2013;10:e1001442.
- Alderman H, Behrman JR, Grantham-McGregor S, et al. Economic perspectives on integrating early child stimulation with nutritional interventions. *Ann N Y Acad Sci* 2014;1308:129–38.
- Lakkis NA, Osman MH, Aoude LC, et al. A pilot intervention to promote positive parenting in refugees from Syria in Lebanon and Jordan. *Front Psychiatry* 2020;11:257.
- Singla DR, Kumbakumba E, Aboud FE. Effects of a parenting intervention to address maternal psychological wellbeing and child development and growth in rural Uganda: a community-based, cluster randomised trial. *Lancet Glob Health* 2015;3:e458–69.
- Rockers PC, Fink G, Zanolini A, et al. Impact of a community-based package of interventions on child development in Zambia: a cluster-randomised controlled trial. *BMJ Glob Health* 2016;1:e000104.
- Chen Y, Wu Y, Dill S-E, et al. Effect of the mHealth-supported healthy future programme delivered by community health workers on maternal and child health in rural China: study protocol for a cluster randomised controlled trial. *BMJ Open* 2023;13:e0065403.
- Britto PR, Lye SJ, Proulx K, et al. Nurturing care: promoting early childhood development. *The Lancet* 2017;389:91–102.
- Shawar YR, Shiffman J. Generation of global political priority for early childhood development: the challenges of framing and governance. *The Lancet* 2017;389:119–24.
- Britto PR, Engle PL, Super CM. *handbook of early childhood development research and its impact on global Policy*. In: *Building and strengthening national systems for early childhood development. Handbook of early childhood development research and its impact on global policy*. New York, NY, US: Oxford University Press, 2013: 443–66.
- Richter LM, Daelmans B, Lombardi J, et al. Investing in the foundation of sustainable development: pathways to scale up for early childhood development. *The Lancet* 2017;389:103–18.
- Jaskiewicz W, Tulenko K. Increasing community health worker productivity and effectiveness: a review of the influence of the work environment. *Hum Resour Health* 2012;10:38.
- Atif N, Bibi A, Nisar A, et al. Delivering maternal mental health through peer volunteers: a 5-year report. *Int J Ment Health Syst* 2019;13:62.
- All-China Women's Federation. Women of China - All China Women's Federation, . 2023Available: <https://www.womenofchina.cn/> [Accessed 19 Mar 2023].
- Grantham-McGregor S, Smith JA. Extending the Jamaican early childhood development intervention. *Journal of Applied Research on Children: Informing Policy for Children at Risk* 2016;7.
- Maselko J, Sikander S, Bhalotra S, et al. Effect of an early perinatal depression intervention on long-term child development outcomes: follow-up of the thinking healthy programme randomised controlled trial. *The Lancet Psychiatry* 2015;2:609–17.
- All-China Women's Federation. Statistical communique of the Ya'An on the 2020 National economic and social development; 2020.
- Hao T, Sun R, Tombe T, et al. The effect of migration policy on growth, structural change, and regional inequality in China. *Journal of Monetary Economics* 2020;113:112–34.
- Wang X-R, Hui EC-M, Choguill C, et al. The new urbanization policy in China: which way forward *Habitat International* 2015;47:279–84.
- Sylvia S, Luo R, Zhong J, et al. Passive versus active service delivery: comparing the effects of two parenting interventions on early cognitive development in rural China. *World Dev* 2022;149:105686.
- Grantham-McGregor SM, Walker SP, Chang SM, et al. Effects of early childhood supplementation with and without stimulation on later development in stunted Jamaican children. *Am J Clin Nutr* 1997;66:247–53.
- Walker SP, Chang SM, Powell CA, et al. Effects of early childhood Psychosocial stimulation and nutritional supplementation on cognition and education in growth-stunted Jamaican children: prospective cohort study. *The Lancet* 2005;366:1804–7.
- Luo R, Emmers D, Warrinner N, et al. Using community health workers to deliver a Scalable integrated parenting program in rural



- China: A cluster-randomized controlled trial. *Social Science & Medicine* 2019;239:112545.
- 42 Sylvia S, Warrinner N, Luo R, *et al.* From quantity to quality: delivering a home-based parenting intervention through China's family planning Cadres. *The Economic Journal* 2021;131:1365–400.
- 43 Sikander S, Ahmad I, Atif N, *et al.* Delivering the thinking healthy programme for perinatal depression through volunteer peers: a cluster randomised controlled trial in Pakistan. *Lancet Psychiatry* 2019;6:128–39.
- 44 Ko P-C, Hank K. Grandparents caring for grandchildren in China and Korea: findings from CHARLS and Klosa. *J Gerontol B Psychol Sci Soc Sci* 2014;69:646–51.
- 45 Yue A, Zhang N, Liu X, *et al.* Do infant feeding practices differ between grandmothers and mothers in rural China? evidence from rural Shaanxi province. *Family & Community Health* 2018;41:233–43.
- 46 Lauber C, Rössler W. Stigma towards people with mental illness in developing countries in Asia. *Int Rev Psychiatry* 2007;19:157–78.
- 47 Seeman N, Tang S, Brown AD, *et al.* World survey of mental illness stigma. *J Affect Disord* 2016;190:115–21.
- 48 Bayley N. Bayley scales of infant and toddler development. In: *PsychCorp, Pearson*. 2006.
- 49 McCoy DC, Waldman M, Fink G. Measuring early childhood development at a global scale: evidence from the Caregiver-reported early development instruments. *Early Childhood Research Quarterly* 2018;45:58–68.
- 50 Briggs-Gowan MJ, Carter AS, Irwin JR, *et al.* The brief infant-toddler social and emotional assessment: screening for social-emotional problems and delays in competence. *J Pediatr Psychol* 2004;29:143–55.
- 51 Kroenke K, Strine TW, Spitzer RL, *et al.* The PHQ-8 as a measure of current depression in the general population. *J Affect Disord* 2009;114:163–73.
- 52 Lovibond PF, Lovibond SH. The structure of negative emotional States: comparison of the depression anxiety stress scales (DASS) with the Beck depression and anxiety inventories. *Behav Res Ther* 1995;33:335–43.
- 53 Mindell JA, Gould RA, Tikotzy L, *et al.* Norm-Referenced scoring system for the brief infant sleep questionnaire. *Sleep Medicine* 2019;63:106–14.
- 54 Kariger P, Frongillo EA, Engle P, *et al.* Indicators of family care for development for use in Multicountry surveys. *J Health Popul Nutr* 2012;30:472–86.
- 55 Frongillo E, Sywulka S, Kariger P. *UNICEF psychosocial care indicators project. Final report to UNICEF.* Ithaca: Cornell University Division of Nutritional Sciences, 2003.
- 56 Oates J, Gervai J, Danis I, *et al.* Validation of the mothers' object relations scales short-form (MORS-SF). *J Prenat Perinat Psychol Health* 2018;33:38–50.
- 57 Kazarian SS, McCabe SB. Dimensions of social support in the MSPSS: factorial structure, reliability, and theoretical implications. *J Community Psychol* 1991;19:150–60.
- 58 Luo J, Wang M-C, Gao Y, *et al.* Refining the parenting stress index–short form (PSI-SF) in Chinese parents. *Assessment* 2021;28:551–66.
- 59 Kendall S, Bloomfield L. Developing and validating a tool to measure parenting self-efficacy. *J Adv Nurs* 2005;51:174–81.
- 60 Crnic KA, Booth CL. Mothers' and fathers' perceptions of daily Hassles of parenting across early childhood. *Journal of Marriage and the Family* 1991;53:1042.
- 61 O'Connor M, Casey L. The mental health literacy scale (MHLS): A new scale-based measure of mental health literacy. *Psychiatry Research* 2015;229:511–6.
- 62 Hua J, Li Y, Ye K, *et al.* The Reliability and validity of Bayley-III cognitive scale in China's male and female children. *Early Hum Dev* 2019;129:71–8.
- 63 Li Y, Tang L, Bai Y, *et al.* Reliability and validity of the Caregiver reported early development instruments (CREDI) in impoverished regions of China. *BMC Pediatr* 2020;20:475.
- 64 Liang S-Y, Tsai H-W, Wu Y-Y, *et al.* Reliability and validity of the traditional Chinese translation of the brief infant-toddler social and emotional assessment. *Early Hum Dev* 2020;151:105162.
- 65 Hamadani JD, Mehrin SF, Tofail F, *et al.* Integrating an early childhood development programme into Bangladeshi primary health-care services: an open-label, cluster-randomised controlled trial. *The Lancet Global Health* 2019;7:e366–75.
- 66 Wu Y, Levis B, Riehm KE, *et al.* Equivalency of the diagnostic accuracy of the PHQ-8 and PHQ-9: a systematic review and individual participant data meta-analysis. *Psychol Med* 2020;50:1368–80.
- 67 Jiang Q, Dill S-E, Sylvia S, *et al.* Parenting centers and Caregiver mental health: evidence from a Large-Scale randomized controlled trial in China. *Child Dev* 2022;93:1559–73.
- 68 Jiang Q, Guo Y, Zhang E, *et al.* Perinatal mental health problems in rural China: the role of social factors. *Front Psychiatry* 2021;12:636875.
- 69 Zhao J, Zhang Y, Jiang F, *et al.* Excessive screen time and Psychosocial well-being: the mediating role of body mass index, sleep duration, and parent-child interaction. *J Pediatr* 2018;202:157–62.
- 70 Huang Y-S, Paiva T, Hsu J-F, *et al.* Sleep and breathing in premature infants at 6 months post-natal age. *BMC Pediatr* 2014;14:303.
- 71 Bradley RH, Corwyn RF. Caring for children around the world: A view from HOME. *Int J Behav Dev* 2005;29:468–78.
- 72 Zhao Y, Strauss J, Yang G, *et al.* CHINA HEALTH AND RETIREMENT LONGITUDINAL STUDY – 2011-2012 NATIONAL. BASELINE USERS: GUIDE.
- 73 Bhopal SS, Roy R, Verma D, *et al.* Using the mothers object relations scale for early childhood development research in rural India: findings from the early life stress sub-study of the SPRING cluster randomised controlled trial (SPRING-ELS). *Wellcome Open Res* 2021;6:54.
- 74 Zhou K, Li H, Wei X, *et al.* Reliability and validity of the multidimensional scale of perceived social support in Chinese mainland patients with methadone maintenance treatment. *Compr Psychiatry* 2015;60:182–8.
- 75 Wang Y, Wan Q, Huang Z, *et al.* Psychometric properties of multi-dimensional scale of perceived social support in Chinese parents of children with cerebral palsy. *Front Psychol* 2017;8:2020.
- 76 Dai Y, Ouyang R, Li L, *et al.* Parental self-efficacy in managing the home care of children with Hirschsprung's disease or Anorectal malformation: development and validation of a new measure. *J Psychosom Res* 2019;123:109726.
- 77 Chen S, Chen K, Wang S, *et al.* Initial validation of a Chinese version of the mental health literacy scale among Chinese teachers in Henan province. *Front Psychiatry* 2021;12:661903.