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Evaluation on the Effectiveness on the Implementation of WHO-CST Programme in Hong Kong: A RCT Protocol

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RCT Registration Mata Data
Registration Platform: Chinese Clinical Trial Registry
Registry Name: World Health Organization Caregiver Skills Training (WHO-CST) Programme for Hong Kong Chinese families of young children with developmental delays or Autism Spectrum Disorders – Phase Three: evaluation of the pilot implementation

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Abstract

Introduction This protocol aims to provide data collection methods, RCT design and analytical framework to evaluate the effectiveness of the worldwide programme WHO-CST in Hong Kong, which provides intervention to caregivers with children having symptom(s) of Autism spectrum disorder (ASD).

Methods and analysis In present study, 120 eligible caregiver-child dyads will be recruited and randomly assigned in experimental and wait-list-control groups. A RCT design will be adopted to compare the caregivers’ skills and knowledge in handling their ASD-prone children between the two groups. Assessments will be given at the beginning of the WHO-CST programme, at the end of the programme (after 12-training sessions), and about one month after the end of the programme. The measurement will include the Joint Engagement Rating Inventory (JERI) developed by WHO experts to gauge how parents engage their children in a 10-minute video recording their dyadic interaction and behaviors in a definite play setting. A set of other measurements on the caregivers’ experience of using intervention skills and their enhancement of knowledges will also be measured.

Ethics and dissemination Ethics approval has already been sought from the Human Research Ethics Committee, The University of Hong Kong. The final findings of this study will be disseminated through public reports, peer-reviewed publication or conference launched for the WHO-CST programme.

Chinese Clinical Trial Registry number: This RCT practice has been registered at Chinese Clinical Trial Registry in July 2020 (No.: ChiCTR2000034585).
Strength and Limitation

- Although WHO-CST is a worldwide programme which has been launched in over 20 cities for a couple of years, this study is an attempt to evaluate the programme through a robust RCT design in an advanced city (Hong Kong).
- Most of the evaluation on these kinds of programmes were based on self-administrative survey or observatory checklist filled by trainers. This study takes an initiative to rate the trainee’s outcome through a video recording the game play between the trainee (the caregiver) and their children in a definite environment setting.
- Possible dropout from the programme is foreseeable since parents of children having ASD symptoms in Hong Kong are suffered from enormous stress and occupied by their own jobs.
- The original WHO-CST programme was delivered by face-to-face lectures and tutorial with actual home-visit sessions. Under the pandemic of COVID-19, face-to-face lessons are sometimes prohibited by the government or the university. Therefore, our WHO-CST lessons will be probably delivered in the form of distanced course (e.g. by ZOOM), and the home-visits will become sessions situated in the University of Hong Kong.
Introduction

The DSM-5 defined Autism spectrum disorder (ASD) as persistent deficits in social communication and social interaction across multiple contexts, but in clinical context, it usually refers to a set of various neurodevelopment disorders, which can possibly include autism, Asperger syndrome, pervasive developmental disorder not otherwise specified (PDD-NOS), and other similar conditions.[1] Survey figures of diagnosed ASD cases have been raised worldwide in the last two decades. The Autism and Developmental Disabilities Monitoring (ADDM) Network estimated the prevalence of ASD among children aged 8 years was 18.5 per 1,000 children in eleven selected states in America in 2016, while other recent reports from the ADDM network stated that in United States, the 4-year-old ASD prevalence and the 8-year-old ASD prevalence were 13.4 per 1,000,[2] and 16.8 per 1,000, respectively.[3] These figures have been doubled when compared to those reported in the past 10 years (i.e., 6.7 per 1000).[3] A recent meta-analysis in 2020 found that the pooled estimate of ASD prevalence was 0.36% in nine selected Asian countries3 which was much higher than that in similar analysis in 2010 (0.15%),[1] and the pooled estimate of ASD prevalence in mainland China was about 0.39% in a meta-analysis at 2018.[4]

Taking care of children who have ASD symptoms can be difficult, especially when they may exhibit one or more of the core symptoms, such as impairments in social interactions, communication and behaviour malfunctioning.[5] Many children having ASD children were found co-occurring intellectual disability (intelligence quotient [IQ] ≤70),[6] or behavioural problems, such as noncompliance, aggression, and self-injury.[7] As children with ASD symptoms usually have limited capacities of acquiring daily living skills, many parents face challenges in parenting, which can severely impact family functioning and their psychological well-being.[8] This can create stress to caregivers since taking care their children who have ASD may reduce their own ability to socialize with other and further bring negative impact on the relationships with their spouses or partners.[9] In the context of atypical neurodevelopment, ASD and intellectual disabilities can be associated with

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3 The nine countries were China, Korea, India, Lebanon, Bangladesh, Iran, Israeli, Nepal and Sri Lanka.
altered parental responding and directiveness towards the child, possibly due to parents’ difficulty in interpreting child’s behaviour accurately or because the child has poorly regulated interaction and attention.[10]

**Children with ASD in Hong Kong**

In the case of Hong Kong, there was no official estimation on the number of ASD prevalence in the whole population, but several related statistics could be retrieved from reports of different organizations and government departments. For instance, number of students with autism spectrum disorders in mainstream public schools rose from 2,050 in 2010, to 8,710 in 2018.[11] In primary schools, 24% of 22,980 students who have special needs were diagnosed as having ASD in 2018.[12] With reference to the latest Mental Health Review Report, the caseload of Child and Adolescent Psychiatric Services under the Hospital Authority for ASD alone increased from about 5,000 in 2011/12 to about 9,000 in 2015/16, comprised over 60% of the caseload of the Services.[13] The number of children newly diagnosed with ASD in the Child Assessment Service of the Department of Health has increased close to three times from 755 in 2006 to 2021 in 2015, the number of preschoolers with significant developmental disorders has also been doubled.[14] All abovementioned evidence showed that the figures of children having been diagnosed as having ASD in Hong Kong have been soared rapidly in the last two decades.

Living in a Chinese society like Hong Kong, parents of children with ASD diagnosed have to face strong pressure from the society since the traditional Chinese culture, which always emphasizes the association of parent’s competence with children’s academic achievement, reinforces discrimination on having a child with disability.[15] Parents tended to internalize such external criticism (as affiliate stigma) on their children, and assume their own responsibility on the stigmatic condition, and believe that they may be utterly uncontrollable to their children’s condition and corresponding stigmatization. Such affiliate stigma brings psychological and parenting stress to the parents, and consequentially damages their mental health and psychological well-being.[16-17] delays formal diagnosis as a denial to children’s ASD symptoms, and sometimes hinders their children’s involvement in community participation.[18-19]

Cost of available private services (including diagnosis) for children with ASD symptoms was high and less affordable by lower class in Hong Kong.
Meanwhile, although the government provides lower-cost public services such as early diagnosis and medical treatment through Child Assessment Centres and NGO services at district level for children under age 12, they were not sufficient to fulfill the overwhelming demand, resulted in a rather long waiting period (about 12 to 24 months) for initial developmental assessment.[21-22] The delay of diagnosis can bring ramification on children’s school enrollment and procrastinate necessary treatment and services.[21] Self-stigma, anxiety and hesitation on seeking formal diagnosis and services may also attribute to parent’s lack of awareness and knowledge on ASD and developmental delay. Although Hong Kong has a relatively advanced and well-organized public health system compared with other less developed cities, parents may still not have sufficient knowledge and information on accessing clinical professionals and services at their living districts.[23]

Therefore, at the time being for parents who suspects that their children may have ASD are waiting for receiving formal diagnosis, pre-assessment intervention can be offered to enhance their caregiving skill and knowledge on handling situation of ASD children. Services or interventions which allow parents to communicate with professionals and other parents having similar caregiving experience can also moderate their anxiety, since social support and teaching parents to have positive perception can ameliorate mental and relational well-being among parents of children having ASD.[16, 24] Well organized pre-assessment service can also be associated with a reduced duration of diagnostic process for children. Offering adequate and relevant information in pre-assessment period can be likely to reduce total duration of the assessment process.[25] Recent review on services prepared for ASD children also suggested that provision of pre-assessment information workshops and earlier intervention to parents can reduce their anxiety and let them become more well-prepared for formal diagnosis and services.[23]

Furthermore, there is growing evidence supporting that enhancement in parental skills in communication, engagement and mitigating autistic mannerisms can be achieved through appropriate intervention, leading to better developmental and behavioural outcomes of ASD children, and also better family functioning.[26-27] Involving parents in implementing interventions to their children allows consistent handling, and ensures that the intervention is appropriate in enhancing child’s earliest social and communicative development.[10]
Since August 2015, the JC A-Connect Family Support Team (hereinafter, “the Team”) was set up to provide early pre-assessment intervention and various training programmes for parents who suspected that their children may have ASD. The team was funded by the Hong Kong Jockey Club Charities Trust and wholly managed under the Faculty of Social Sciences, the University of Hong Kong, and the programmes launched were co-operated with several NGOs in Hong Kong (i.e., Caritas-HK, Heep Hong Society, and SAHK). A few small-scale evaluative studies have been conducted to examine the efficacy of different programmes, and these studies showed small within-group effect sizes on the reductions in child’s problematic behaviours, parenting stress, as well as on the improvements of perceived social support, parenting competence and mental health (Cohen’s $d$ ranged 0.11-0.22; 226 families). While the Team appreciated the creativity and commitment of the NGOs in designing innovative strategies to address the needs of families of children with ASD, the non-standardized programme implementation and non-comparable evaluation design resulted in difficulties on assessing the successfulness of the programmes and failed to inform any measures on improving these set of programmes. Under consideration of these defaults, at the beginning of 2019, the Team began to adapt a standardized training programme titled “World Health Organization - Caregiver Skills Training” (WHO-CST) in Hong Kong, which was co-created and recommended by WHO and Autism Speaks. Eight major NGOs (Caritas Hong Kong, Heep Hong Society, SAHK, the Salvatory Army, the Tung Wah Group of Hospitals, the Hong Kong Sheng Kung Hui Welfare Council, YWCA, and the New Life) which have provided services for children with ASD also joined the project and implemented the WHO-CST programme in various districts of Hong Kong under the coordination of the Team.

The WHO-CST Programme

Developmental delays/disorders in young children are identified as a public health priority. In 2009, the World Health Organization (WHO) launched the mental health Gap Action Programme (mhGAP) aiming at bridging up the treatment gaps for mental, neurological and substance use disorders worldwide.[28] In the latest mhGAP intervention guide, WHO and Autism Speaks co-created and recommended that the Caregiver Skills Training (CST) programme should be widely implemented in the management of children with possible ASD symptoms, intellectual disabilities and pervasive developmental
The WHO-CST materials were developed based on findings of several meta-analyses [26, 27, 30] and in consultation with experts and parents' association from all WHO regions and support from Autism Speaks.[27] The aim of the WHO-CST programme is, on one hand, to train non-specialist social service providers, such as social workers.

The WHO-CST programme package, hence, includes the following characteristics:

- a multi-component intervention in which its content is theoretically based on behavioural approaches for promoting shared engagement and communication, such as Joint Attention Symbolic Play Engagement Regulation (JASPER), Pivotal Response Treatment (PRT) and Discrete Trial Training (DTT), as well as positive parenting approaches for promoting positive child behaviour, and/or management of challenging behaviour;
- a programme consisted of nine group sessions and three individual home visits, focusing on training parents on how to use every day play and home activities and routines as opportunities for learning and development;
- a programme required vigorous fidelity monitoring (e.g., video-recording facilitators’ performance) and comprehensive evaluation on both parental and child outcomes by self-reports and through blinded, trained assessors;
- a task-shifting approach in which non-specialists, such as social workers, teachers and community leaders, can train parents to deliver interventions for promoting their child’s development effectively; and
- a trans-diagnostic approach, so that children who have not met the diagnostic criteria for ASD or other pervasive developmental disorders (such as developmental delays) could be benefited from the programme.

Under the framework of implementation science, the WHO-CST programme was in the stage of pilot-testing in more than 30 countries at 2018 [31] and several randomized controlled trials were underway in Pakistan and other countries.[32]

In the actual implementation, the WHO-CST programme consisted of 12 sessions, which was comprised of:

1. 9 weekly group-based sessions (each session will last approximately for...
2.5 to 3 hours), 6 to 8 caregivers in a group, led by 2 facilitators who have received a 5-day training by WHO staffs and Autism Speaks, and,

2. 3 home visits (each visit will last approximately for 1 to 1.5 hours) occurred before the 1st session, between session 4 and 5, and after the last session, conducted by 2 facilitators to each caregiver’s family.

The themes and detailed objectives of each session were listed in Table 1.

Table 1. Session-by-session outline of the WHO-CST programme

| Theme | Learning objectives for the caregivers |
|-------|---------------------------------------|
| Home visit 1 | • To build rapport with the family  
| | • To learn about the child’s developmental competencies  
| | • To help the caregivers to set goals for the programme, successfully implement the CST strategies and troubleshoot challenges |
| Session 1A - Introduction and getting children engaged | • To feel welcomed and to know the expectation of the programme  
| | • To begin to develop an understanding that the cause of developmental delays could be unknown  
| | • To understand all children can learn new skills and everyday activities are opportunities to help their child to develop  
| | • To begin to demonstrate an understanding how to set up the activity, offer choices and position the caregiver directly in front of the child |
| Session 1B - Keeping children engaged | • To develop and understand that the cause of developmental delays could be unknown  
| | • To continue to demonstrate an understanding how to set up the activity, offer choices and position the caregiver directly in front of the child  
| | • To begin to demonstrate an understanding of following the child’s interests and providing praise |
| Session 2 - Helping children share engagement in play and home routines | • To appreciate how playing helps children to learn and to build relationships with others  
| | • To know how to choose the right time and set up a play or home activity routine  
| | • To know to follow the child’s interest and imitate his play  
| | • To know how to join in by taking turns in the activity  
| | • To know to add a new step or modify the routine |
| Home visit 2 | - To review child’s individualised goals, home practice and play and home routines  
| (between Session 2 and 3/4) | - To improve confidence in applying the strategies introduced in group sessions so far (i.e. set up play and home routines; create opportunities for the child to communicate)  
| | - To identify additional needs of the family and child  
| | - To boost motivation to continue attending  
| Session 3 – Understanding communication | - To identify the ways that children communicate with and without using words  
| | - To know how to look, listen, and respond to children's interests and all communication  
| | - To know how to look and listen to children’s behaviour to figure out the message the child is trying to communicate  
| | - To understand their child’s target communication skill and be able to provide an example  
| | - To know how to respond to children’s communication with a gesture and words at the child’s language level even if the child uses unclear or odd communication  
| | - To know how to wait to give children time to respond and room to initiate communication  
| Session 4 – Promoting communication | - To identify when children communicate to share and when they communicate to request  
| | - To notice and respond to children’s comments to share and their requests  
| | - To respond by imitating and expanding a child’s communication  
| | - To demonstrate how to create moments for children to share (wait, show and say, wait)  
| | - To demonstrate how to create moments for children to request (choices, and small pieces)  
| Session 5: Preventing challenging behaviour, helping children stay engaged and regulated | - To identify when children are regulated (cool) and “dysregulated” (warm or hot)  
| | - To understand the four reasons for challenging behaviour: To communicate, to escape/avoid, to get attention, and to get access to sensation  
| | - To identify the three parts of behaviour (before, during, after)  
| | - To identify signals for challenging behaviour (before the behaviour)  
|
• To use a mood thermometer to help our children understand how they are feeling
• To scan the environment to reduce chances for challenging behaviour
• To give visual and spoken warnings before changes happen

Session 6: Teaching alternatives to challenging behaviour
• To learn to use a picture schedule to understand the routine
• To demonstrate how to respond to challenging behaviour to get access to a tangible
• To demonstrate how to respond to challenging behaviour to get attention by ignoring
• To demonstrate how to respond to challenging behaviour to avoid or stop by setting clear expectations and following through on those expectations
• To understand that sensation seeking behaviours can be reduced by replacing the challenging behaviour with a more socially appropriate behaviour

Session 7: Teaching new Skills in Small Steps and Levels of Help
• To learn to select an appropriate target skill from a larger routine
• To understand that learning each target skill will take repeated practice and the goal is to link these small steps into one big task over time
• To understand how to appropriately apply the lowest level of help to support the child
• To remember to stay active in the routine by taking turns and positive by rewarding the child with praise and comments throughout the routine

Session 8: Problem Solving and Self Care
• To recognize their progress in the course and set goals for the future.
• To appreciate the importance of self-care.
• To know basic self-care strategies and understand the importance of social support and engaging in meaningful and enjoyable activities.
• To know how to use problem solving to help themselves
• To know how to expand current routines to keep them going once the programme ends

Home visit 3 – after Session 8
• To identify the areas where most help is needed and start choosing independently appropriate strategies
To learn to apply selected strategies from sessions 1-7
To carry out up play and routine activities that are appropriate for the child’s individualised goals

The group-based sessions in delivering CST materials focus on training caregivers to improve communication skills, shared engagement in activities and routines with caregiver-child dyads, behavioural skills and problem-solving ability in caring for a child with developmental delays and/or disorders. Each group session consists of the following key activities:

- Brief wellness activity, e.g., abdominal breathing exercise
- Review of key CST messages and home practice
- Sharing of a case scenario related to the child’s developmental difficulties
- Group discussion and experience sharing
- Skills demonstration by facilitators
- Live practice among caregivers in pairs
- Establish plan for home practice and session review

Home visits provide an opportunity to build rapport with the family, learn about the child’s developmental competencies and behaviour and the home family environment, help the caregivers to set goals for the programme, successfully implement the strategies that have been introduced to during the group sessions, troubleshoot challenges that have been encountered by caregivers and identify any additional needs to the family.

Social workers or clinical psychologists had to receive training from WHO experts and passed tests assessing their skills on interacting and communicating with children with ASD symptoms in order to be qualified in teaching the WHO-CST programme. These accredited master trainers were allowed to launch the WHO-CST programme themselves, and train other trainers to implement the programme. On the contrary, the trainers instructed under these accredited master trainers were allowed to deliver the programme to parents, but they were not allowed to train other trainees.

In the case of Hong Kong, all teaching materials in the WHO-CST programme were translated into Traditional Chinese. Lessons and guidance in the home visit were all conveyed in Cantonese, which is the colloquial language used by the major population in Hong Kong. During the COVID-19 pandemic
from the beginning of 2020, all the group-based sessions were delivered in the way of video lectures and tutorials (e.g. small-group discussions) through ZOOM, and the home visit session, which investigated how parents interacted with their children, were taken place in training room situated in the University of Hong Kong.

The Present Study

This study aims to, first, evaluate the usefulness of the WHO-CST intervention in the Chinese-based community of Hong Kong through a randomized controlled trial (RCT) design, and second, examine potential factors hindered or promoted the usefulness of the WHO-CST programme.

Participants

Caregiver-child dyads as potential participants will be recruited through advertisement on social media and promotion at district level through cooperating NGOs. The recruited caregiver-child dyads have to fulfill a set of inclusion criteria in order to be admitted into the WHO-CST programme.

For caregivers, they should be:

- Hong Kong residents
- at least 18 years or above,
- the primary caregiver who is responsible for the role of parenting the child, this could be biological parent (father or mother), guardian or other adult family member (i.e., the same caregiver who will attend the WHO-CST programme if she/he agrees),
- living together with the target child,
- able to communicate in Cantonese,
- able to read and write basic Traditional Chinese, and
- able to stay in Hong Kong for at least six months for most of the time for home visits and 9 sections of face-to-face group intervention and accessible by phone.

In addition, to ensure the adherence of WHO-CST programme, these caregivers shall allow the following procedures to be carried out during the programme implementation:
agree to take their children to the University of Hong Kong to attend the three home visit sessions and record videos for assessing their interaction and communication with their children

agree to be recorded by ZOOM in the 9 group-based sections of intervention.

For children who are eligible to participate the WHO-CST programme in Hong Kong, they should be:

between 2 and 6 years old,

screened positive on Modified Chinese version of the Checklist for Autism in Toddlers (C-CHAT-23) [33] or,

suspected to display symptoms or behaviours of autism spectrum disorder, such as persistent deficits in social communication and social interaction across multiple contexts and restricted, repetitive patterns of behaviours, interest, or activities, or,

suspected to display symptoms or behaviours of communication disorder, such as persistent difficulties in the acquisition and use of language across modalities and language abilities are substantially and quantifiably below those expected age, or,

the above symptoms or behaviours are the primary concerns of developmental issues the child face as reported by caregivers or clinicians (children who are suspected to co-morbid other conditions, such as intellectual disability, attention deficit hyperactivity disorder, specific learning disorder and motor disorder are also eligible if these other conditions are not primary concerns of developmental issues)

Sample Size Estimation

This study targets to test the clinical effect of the treatment on both self-reported outcomes by caregivers and rater-assessed outcomes of caregiver-children interaction and compare these outcomes between the treatment group and wait-list-control group. The Team assumes a conservative effect size estimate of 0.30 (i.e., moderate effect size) for the outcome measures, 80% power at 5% two-tailed significance level; and 10% attrition rate. Based on Karlsson, Engebretsen and Dainty’s [34] formula and suggestions, 120 caregiver-child dyads are proposed to be recruited and should be representative to draw significant results in the final analysis. Participated caregiver-child dyads will be
randomized to the intervention or to a wait list at 1:1 ratio: 60 caregiver-child dyads will be randomly assigned to a treatment group to receive WHO-CST training whereas another 60 caregiver-child dyads will be randomly assigned to a wait-list-control condition. As the final analysis will be done under the intent-to-treat principle, the dropout participants will also be included in the analysis.

Randomized Control Trial Design

Participated caregiver-child dyad will be enrolled by accredited trainers of the WHO-CST programme based on the selection criteria listed before. Researcher who generates randomized sequence for RCT is independent from the research team who recruits participant. The researcher will put caregivers name into a Python list (in random order, expected 120 caregivers) and use the Python function “sample()” to randomly extract 60 caregivers without replacement. The flow of the RCT design is shown in Figure 1. Before formally starting the WHO-CST intervention, both groups will complete the 1st assessment as the baseline for group comparison. Then, the treatment group will receive 12 weeks of WHO-CST intervention after the screening tasks, while the wait-list-control group will wait for intervention at this 12-week waiting period. The 2nd assessment of both groups come immediately after the completion of treatment group’s intervention. To investigate the persistent effect of the intervention, a follow-up assessment will be implemented 30 days after the completion of the treatment group’s intervention. In other words, the wait-list-control group will take all the three assessments parallelly with the treatment group and will receive the intervention afterwards. Both participants in the treatment group and wait-list-control group will be blind for their assignment to the RCT experiment. The whole RCT is supposed to be completed within seven months, including the intervention to wait-list-control group.

Figure 1. Flow diagram of the RCT design in this study

Since the WHO-CST in Hong Kong is a sustained programme and multiple-parallel training sessions are opened continuously throughout the two years of operation, it is normal that some caregivers have to wait for 3 to 6 months to receive the training. Also, it is a normal practice to have multiple assessments before and during the WHO-CST sessions. The assessment, training content and practices are all identical between the treatment group and the wait-list
group. Therefore, the caregivers will only know that they are assigned into different time slots of training, but will not know whether they are in the treatment group or in the wait-list-group.

Hypothesis

This study hypothesizes that, (1.) after the intervention through the WHO-CST training, treatment group’s caregiving knowledge and skills will be enhanced more than the wait-list-control group and, (2.) after the intervention, the children of treatment group parents will have less misbehavior than those of the wait-list-control group parents.

Assessment Tools

The assessment tools in this study includes parents’ self-reported on-line survey and video-taking of parent-children playtime in pre-set scenarios in training room at the University of Hong Kong. During the playtime, toys, duration of the playtime and instructions to parents are all standardized to minimize factors of circumstance.

Measurements in Parents’ Self-Reported Survey

Participants will be invited to complete a questionnaire in soliciting their sociodemographic information and their child’s characteristics at the 1st Assessment. Then, in each round of assessment, both the treatment groups and the wait-list-control groups will be requested to complete the following outcome measures in the self-reported survey. All the outcome measures have been translated into Traditional Chinese.

Caregivers’ Knowledge and Skill

The Caregiver Knowledge and Skills Test is designed by WHO expects who led the worldwide WHO-CST programme and will be used to assess the knowledge and skills of the caregivers related to WHO-CST programme materials. Caregivers will be invited to rate 24 statements on a 5-point Likert scale ranging from 1 (I strongly disagree) to 5 (I strongly agree), for example, “My child has more opportunities to learn when we are focusing attention on
same toy or activity”. Further, caregivers will be asked to indicate their confidence level (13 statements) on a 5-point Likert scale ranging from 1 (not confident) to 5 (very confident), such as “I feel confident in using pictures to help my child follow a routine”. Caregivers will also be asked to complete 3 scenario-based short answer questions.

**Caregivers’ Experience on Using Strategies**

A set of questions will be used to evaluate the caregivers’ experiences with the intervention strategies that they learnt during the WHO-CST programme, in terms of their level of confidence, comfort in using the strategies, as well as how difficult, effortful and natural the caregiver perceives the strategies.[35]

**Caregivers’ Quality of Life**

Parents have to report their quality of life in each assessment through filling in the General Health Questionnaire-12 (GHQ-12). The GHQ-12 is a widely used and easy-to-understand instrument for measuring parents’ psychological strain, particularly in aspects of social dysfunction and anxiety / depression. The Chinese version of GHQ-12 have been well-validated in several studies. [36,37]

**Children’s Misbehavior**

The suspected ASD children’s misbehaviors will be gauged mainly by two scales. The first one is the Eyberg Child Behavior Inventory (ECBI) which is a 36-item multi-dimensional, parent-rating scale on the perception of their children’s conduct problems, especially for children 2 to 17. Parents are asked to rate how often each stated behavior occurs on a 7-point frequency-of-occurrence scale, which generate the “intensity score”. They are also required to indicate whether the stated behavior is still currently a problem to them, which generate the “problem score”. High scores represent high frequency and high number of children’s disruptive behavior in their daily life. The Chinese version of ECBI have been validated by the Education Bureau (formerly known as the Education and Manpower Bureau), HKSAR.[19]

The second scale is the Chinese version of the Modified Checklist for Autism in Toddlers (Chinese M-CHAT). This 23-item scale is a common and easy-to-administered screening tool for identification of autistic children, which addressed on aspects like children’s social relatedness, joint attention, bringing objects to show parents and their responses to other’s calling. Wong et al.’s study confirmed the validity of this scale on young children and its reliability for
Hong Kong caregivers. [33]

**Measurements on Video-recoded Playtime**

For each of the participating parent-dyad, they have to take videos on a standardized 10-minute play scenario at each assessment time (the 1st assessment, the 2nd assessment and the follow-up assessment). All the videos will be rated by the Joint Engagement Rating Inventory (JERI). [38] JERI was designed by experts cooperating the WHO-CST, and was targeted to characterize both child and caregiver’s activities during the Communication Play Protocol. [39] The scale is adapted to rate child’s engagement states as well as various aspects of the children’s and caregiver’s behavior and of their shared activities. Raters of our studies have to view the video records of the 10-minute play scene in the caregiver-child interaction using skills acquired in the WHO-CST training, and they have to make judgment about the interaction using seven-point rating scales on ten items:

1. Unengaged
2. Joint Engagement
3. Stereotyped, Restricted, and Repetitive Behaviours
4. Attention to Caregiver
5. Initiation of Communication
6. Expressive Language Level and Use
7. Scaffolding
8. Following in
9. Caregiver’s Affect
10. Fluency and Connectedness

These ten items address on various aspects of caregiver-child interaction including child’s engagement state (e.g. joint engagement), child’s activities (e.g. initiation of communication), caregiver’s supports on child’s activities (e.g. scaffolding), caregiver’s attention on child’s focus (e.g. following in) and dyadic interaction (e.g. fluency and connectedness).

To maintain fairness and reliability of the rating practices, the rating team will not be members of the research team of this study. The rating team are particularly recruited for rating the videos and have no direct contact nor interaction with any participants of the project. The rating team will attend a distanced training course taught by WHO experts on how to adopt the JERI on
assessing caregiver-child gameplay videos. There will be 5 sessions (about 2 hours) in the whole training course. The trainers from WHO will ensure that the raters will be qualified to use JERI in rating the videos.

To ensure the reliability of the coding scheme, one-third of the videos will be blindly sent to two raters for rating, and inter-rater reliability of each item in the JERI will be calculated.

**Data Analysis**

Two sources of data will be collected: (1) data from the online survey platform, (2) data collected from the JERI ratings video recording caregiver-child interactions. For the variables which presented as continuous or count data, the between group mean differences, the standard deviation, the range and the possible range (as provided in the instrument), at different time points of assessment will be reported. Given the intent-to-treat design, all caregiver-children dyads’ data will be contained in the original assignment group, including those who dropped out before the end of the study, and all will take the assessment at any of the three timepoints as possible. All the outcome measurements with continuous variables (i.e., JERI, GHQ12, ECBI, etc.) will be analyzed using linear mixed models (LMM) with random intercept and slope parameters, where appropriate, examining the effect of treatment assignment (treatment group versus wait-list-control group), time points of assessment (T1, T2 and T3), and their interaction on outcome. The reason of using the LMM is because of its full-information loaded characteristic which can involve information from all randomized (intent-to-treat) participants, including those with only partial data owing to drop-out or other reasons.[40] LMM are advantageous compared to repeated measures ANCOVA in that they accommodate data of missing time points, hence utilize all available data, and therefore can be considered in our intent-to-treat models. One’s latest assessments before dropout or completion of the programme will be used in the model. The assessment at T2 and its interaction with group and time are the primary interest to test our hypotheses. The LMM analysis will be performed by R package lme4 and glmmTMB.

**Ethical Considerations**

Before the commencement of the study, ethical approval has already been
obtained from the Human Research Ethics Committee, the University of Hong Kong. There is no foreseeable significant psychological distress and any other hazards entailed by the study procedures.

Plan for Obtaining Informed Consent

Written consent will be obtained from all the participants before completing the baseline assessment. The participation is entirely voluntary; every participant maintains every right to withdraw from the study. For the caregivers, they will be further reassured that their participation will not affect the health care and/or social services that the families and their children are currently receiving. The text in the Informed Consent Form will be read to all potential participants (i.e., caregivers) and they will have an opportunity to ask questions and express concerns (e.g., the purpose of video-recording). The minimal time given to the caregivers for consideration after explanation will be 15 to 20 minutes. However, the caregivers can take as much time as needed to consider taking part of the study. In addition, the caregivers will be informed verbally about future publications of the study in the scientific literature. All the information obtained will be as confidential.

Anonymousness and Confidentiality

All data collected will be kept confidential and be used for research purposes only. Each participant will be assigned a unique identification code (ID code). ID codes instead of names of participants will be used and thus, identity of participants would not be disclosed to unauthorized persons. Moreover, the ID codes with names will be stored separately in documents from the collected data.

Data with identifiable information will be kept in a locked cabinet, which can only be accessed by the research team. All personal data and video-recorded files will be stored in password-protected files and encrypted. No data will be stored on personally-owned personal computers or portable storage devices. No personal identifiable information will be reported in any of the reports or publications.

Concerning the video-records made during the home-visit, all the video-records will be uploaded by facilitators to an online platform developed by IT
staffs of Faculty of Social Sciences, the University of Hong Kong. Only researchers have the rights to assess the online platform which is consistently monitored by IT staffs of Faculty of Social Sciences. Therefore, the privacy of participants can be protected.

**Role of Coordinating Team**

The Family Support Team of the JC A-Connect project is subordinated the Faculty of Social Science, The University of Hong Kong. The team is responsible for delivering the clinical services filling the syllabus and standard of WHO-CST, training trainers to deliver the WHO-CST programme at community level, collecting and analyzing data for the evaluation of WHO-CST programme in Hong Kong.

**Limitation**

The aim of this study is to evaluate the implementation of the WHO-CST programme in Hong Kong by measurable and scientific method. This research will involve human participants who are supposed to be caregivers of ASD children (or suspected ASD children). As mentioned at the introduction, parents of ASD children are so stressful in Hong Kong, also it is a common practice in Hong Kong for both parents of a children having their own jobs. There will be possibility that caregivers may drop out from the RCT due to emotional or personal (e.g. time management) reasons. Although our team expected 10% dropout rate in the coming programme, the actual rate is not predictable and may be higher than expected. Our team will try to recruit more participants than the suggested number to prevent the failure of research study causing by the dropout problem.

Another limitation is about the changed mode of the WHO-CST delivered. The original WHO-CST should be delivered by face-to-face lectures and tutorial, and there should be three sessions of actual home-visit for trainers to provide guidance on parent-child interaction. Under the pandemic of COVID-19, face-to-face lessons are sometimes prohibited by the government or the university. Therefore, our WHO-CST lessons will be probably delivered in the form of distanced courses (e.g. by ZOOM), and the home-visits will become sessions situated in the University of Hong Kong. Our evaluation results and the effect of training can only represent an “on-line delivered version” of WHO-CST, but
may not be applicable to traditional face-to-face basis WHO-CST.

**Patient and public involvement** There is no patient and public involvement in the design of this study and recruitment procedure.

**Contributorship statement** W.C.P Wong served as principal investigator of the WHO-CST programme in Hong Kong and designed this research study. S. L. Chow drafted this protocol and revised this manuscript. S. L. is responsible for the data management and analysis of this study. Both authors approved the publication of this protocol.

**Competing interests** The authors declared none competing interests.

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**Data sharing statement** The data of this study will be ready from August 2021. Data will be shared upon reasonable requests and under the approval of the funder.

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Recruitment

Screening

Randomization (120 Dyads)

1st Assessment for Treatment Group (60 Dyads)

Treatment Group (60 Dyads) 12 Weeks Intervention

2nd Assessment for Treatment Group

Follow-up Assessment: 30 days after the completion of the intervention

1st Assessment for Wait-list-control Group (60 Dyads)

Wait-list-control Group (60 Dyads) 12 Weeks Waiting Period

2nd Assessment for Wait-list-control Group

Follow-up Assessment: 30 days after the completion of Treatment Group's intervention

Wait-list-control Group (60 Dyads) 12 Weeks Intervention

12 Weeks Intervention
| Section/Topic     | Item No | Checklist item                                                                                                                                                                                                 | Reported on page No |
|------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| **Title and abstract** |         |                                                                                                                                                                                                             |                     |
|                  | 1a      | Identification as a randomised trial in the title                                                                                                                                                            | 1                   |
|                  | 1b      | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)                                                                                       | 2                   |
| **Introduction** |         |                                                                                                                                                                                                             |                     |
| Background and objectives | 2a      | Scientific background and explanation of rationale                                                                                                                                                           | 3-7                 |
|                  | 2b      | Specific objectives or hypotheses                                                                                                                                                                           | 15                  |
| **Methods**      |         |                                                                                                                                                                                                             |                     |
| Trial design     | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio                                                                                                                         | 14-15               |
|                  | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons                                                                                                           |                     |
| Participants     | 4a      | Eligibility criteria for participants                                                                                                                                                                        | 12-13               |
|                  | 4b      | Settings and locations where the data were collected                                                                                                                                                         | 17-19               |
| Interventions    | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered                                                                        | 8-11                |
| Outcomes         | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were actually administered                                                                            | 17-19               |
|                  | 6b      | Any changes to trial outcomes after the trial commenced, with reasons                                                                                                                                       |                     |
| Sample size      | 7a      | How sample size was determined                                                                                                                                                                              | 15                  |
|                  | 7b      | When applicable, explanation of any interim analyses and stopping guidelines                                                                                                                                  |                     |
| Randomisation:   |         |                                                                                                                                                                                                             |                     |
| Sequence         | 8a      | Method used to generate the random allocation sequence                                                                                                                                                        | 15                  |
| generation       | 8b      | Type of randomisation; details of any restriction (such as blocking and block size)                                                                                                                                 |                     |
| Allocation       | 9       | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 15                  |
| concealment      |         |                                                                                                                                                                                                             |                     |
| mechanism        |         |                                                                                                                                                                                                             |                     |
| Implementation   | 10      | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions                                                                                     | 15                  |
| Blinding         | 11a     | If done, who was blinded after assignment to interventions (for example, participants, care providers, those who administered interventions)                                                               | 16                  |
| Item | Description |
|------|-------------|
| 11b  | If relevant, description of the similarity of interventions |
| 12a  | Statistical methods used to compare groups for primary and secondary outcomes |
| 12b  | Methods for additional analyses, such as subgroup analyses and adjusted analyses |
| 13a  | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |
| 13b  | For each group, losses and exclusions after randomisation, together with reasons |
| 14a  | Dates defining the periods of recruitment and follow-up |
| 14b  | Why the trial ended or was stopped |
| 15   | A table showing baseline demographic and clinical characteristics for each group |
| 16   | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups |
| 17a  | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) |
| 17b  | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |
| 18   | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |
| 19   | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) |
| 20   | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |
| 21   | Generalisability (external validity, applicability) of the trial findings |
| 22   | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |
| 23   | Registration number and name of trial registry |
| 24   | Where the full trial protocol can be accessed, if available |
| 25   | Sources of funding and other support (such as supply of drugs), role of funders |

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).
Evaluation on the Effectiveness on the Implementation of World Health Organisation (WHO) Caregiver skills Training (CST) Programme in Hong Kong: A Randomised Controlled Trial Protocol

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Evaluation on the Effectiveness on the Implementation of World Health Organisation (WHO) Caregiver skills Training (CST) Programme in Hong Kong: A Randomised Controlled Trial Protocol

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Registration Platform: Chinese Clinical Trial Registry

Registry Name: World Health Organization Caregiver Skills Training (WHO-CST) Programme for Hong Kong Chinese families of young children with developmental delays or autism spectrum disorder – Phase Three: evaluation of the pilot implementation

Registration Number: ChiCTR2000034585

Registration Date: July, 2020

Protocol Version: 1.2

Protocol Preprint: https://medrxiv.org/cgi/content/short/2021.05.17.21257327v1
Abstract

Introduction This protocol delineates the research design and analytical framework used to evaluate the effectiveness of the WHO-CST in Hong Kong. The WHO-CST aims to enhance the caregiver skills of parents of children with potential autism spectrum disorders (ASD) and/or developmental delays.

Methods and analysis In this study, 130 eligible caregiver-child dyads were recruited and randomly assigned to the experimental and wait-list control groups. A randomised controlled trial (RCT) design was adopted to compare the changes between the two groups regarding caregivers’ skills, knowledge, and practices when interacting with their children with impairments due to ASD. Assessments were conducted before, immediately after, and one month after the completion of the WHO-CST programme. The primary measurement tool was the joint engagement rating inventory (JERI) developed by WHO experts to gauge how parents engage their children. A 10-minute video recording of their dyadic interaction and behaviours in a defined play setting was used for the measurement. A set of other measurements of caregivers’ knowledge, confidence, and experience of using the caregiving skills were also measured.

Ethics and dissemination Ethics approval was received from the Human Research Ethics Committee (EA1901033), The University of Hong Kong. The final findings of this study will be disseminated through public reports, peer-reviewed publication or at a conference launched for the WHO-CST programme.

Chinese Clinical Trial Registry number This RCT practice was registered at the Chinese Clinical Trial Registry in July 2020 (No. ChiCTR2000034585).
Strengths and Limitations

- The WHO-CST is a programme that has been piloted in over 30 cities, mainly in low- and middle-income countries; this study evaluates the effectiveness of the programme through a RCT design in a high-income and developed Chinese community (Hong Kong).
- To enhance the objectivity of the primary outcome measure, this study uses the ratings of specially trained assessors of changes in interactions between caregivers and their children.
- Under the influence of COVID-19, the programme was delivered through a cloud-based peer-to-peer software platform, while the home visits were conducted in a university setting instead due to the public health concerns.
- Participation and attrition rates may be impacted due to the change in delivery mode of the WHO-CST in Hong Kong.
Introduction

The American Psychiatric Association’s Diagnostic and Statistical Manual, Fifth Edition (DSM-5) defines autism spectrum disorder (ASD) as a condition of persistent deficits in social communication and social interaction across multiple contexts, including Asperger syndrome, pervasive developmental disorder not otherwise specified (PDD-NOS), and other similar conditions.[1] In 2016, the Autism and Developmental Disabilities Monitoring Network estimated the prevalence of ASD among children aged 8 years was 18.5 per 1,000 children in 11 selected states in the United States, while other recent reports from the ADDM network state that in the United States, the 4-year-old ASD prevalence and the 8-year-old ASD prevalence are 13.4 per 1,000,[2] and 16.8 per 1,000, respectively.[3] These figures have doubled when compared to those reported in 10 years ago (i.e., 6.7 per 1000).[3] A recent meta-analysis found that the pooled estimate of ASD prevalence was 0.36% in nine selected Asian countries, which is significantly higher than in a similar analysis conducted in 2010 (0.15%).[1] The pooled estimate of ASD prevalence in mainland China was about 0.39% in a meta-analysis conducted in 2018.[4]

Taking care of children with ASD symptoms can be challenging, especially when they may exhibit one or more of the core and severe symptoms.[5] Many children with ASD are also found to have intellectual disabilities (intelligence quotient [IQ] ≤70),[6] or behavioural problems, such as noncompliance, aggression, and self-injury,[7] and limited capacities to acquire daily living skills. Hence, many parents have parenting issues that severely impact family functioning and psychological well-being.[8] Taking care of children with ASD may also reduce opportunities for socialisation with others and have a negative impact on relationships with spouses or partners.[9,10]

Children with ASD in Hong Kong

According to the Education Bureau, the number of students with an ASD diagnosis in mainstream public schools rose from 2,050 in 2010, to 8,710 in 2018.[11] Furthermore, 24% of 22,980 primary school students with special education needs were diagnosed as having ASD in 2018.[12] With reference to the latest figures from the Hospital Authority, the caseload of Child and Adolescent Psychiatric Services under the Hospital Authority for ASD alone increased from around 5,000 in 2011/12 to about 9,000 in 2015/16, comprising over 60% of the caseload of the services.[13] The number of children newly diagnosed with ASD in the Child Assessment Service of the Department of Health has increased close to three times from 755 in 2006 to 2,021 in 2015, while
the number of pre-schoolers with significant developmental disorders has doubled.[14] The abovementioned evidence demonstrates that the figures for children diagnosed as having ASD in Hong Kong have increased rapidly in the last two decades.

Parents of children with ASD living in Chinese society may face additional social stigma since traditional Chinese culture emphasises the association of parents’ competence with children’s academic achievement and behaviour.[15] Especially, under the COVID-19 pandemic, the closure of schools and day-care centers caused parents to deploy extra effort on keeping their ASD children’s academic performance in progress.[16] Parents tend to internalise such external criticism of their children as affiliate stigma and assume their own responsibility for the stigmatic condition. They believe that they may be unable to control their children’s condition and corresponding stigmatisation. Such affiliate stigma brings psychological and parenting stress to the parents, and consequently damages their mental health and psychological well-being.[17-18] delays formal diagnosis due to denial of children’s ASD symptoms, and sometimes hinders their children’s involvement in community participation.[19-20]

The cost of accessing services for children with ASD symptoms through the private health system can be high for the lower class in Hong Kong if they want early diagnosis and treatment for their children.[15,21] The Hong Kong government provides free to low cost public services such as early diagnosis and medical treatment through Child Assessment Centres and non-governmental organisation (NGO) services at district levels for children under 12 years of age, but they are not sufficient to fulfil the overwhelming demands and as a result, there is a rather long waiting period (from 12 to 24 months) for initial developmental assessment.[22-23] The delay in diagnosis can have ramifications for children’s school enrolment and delay necessary treatment and services.[22] Self-stigma, anxiety, and hesitation in seeking formal diagnosis and services may also contribute to parent’s lack of awareness and knowledge of ASD and also to developmental delay. Although Hong Kong has a relatively advanced and well-organised public health system compared with other less developed cities, parents may not have sufficient knowledge and information about accessing clinical professionals and services in their residential districts.[24]

When parents who suspect that their children may have ASD are waiting to receive a formal diagnosis, pre-assessment intervention can be offered to enhance their caregiving skills and knowledge of early intervention. Services or interventions that allow parents to communicate with professionals and other parents with similar
caregiving experience can also moderate their anxiety since social support and teaching parents to have a positive outlook can mitigate mental and relational well-being issues.[17, 25] Offering adequate and relevant information in the pre-assessment period can reduce the total duration of the assessment process.[26] A recent review of services prepared for children with ASD also suggests that provision of pre-assessment information packages, seminars, and earlier intervention can reduce parents’ anxiety and ensure they are better prepared for formal diagnosis and services.[24]

Furthermore, there is growing evidence that enhancement of parental skills in communication, engagement and mitigation of autistic mannerisms can be achieved through appropriate intervention, which can lead to better developmental and behavioural outcomes for ASD children and also improve family function.[27-28] Involving parents in implementing interventions for their children allows consistent handling and ensures that the intervention is appropriate in enhancing a child’s earliest social and communicative development.[10]

The WHO-CST Programme

In 2009, World Health Organisation (WHO) launched the mental health Gap Action Programme (mhGAP). The programme aims to bridge the treatment gaps for mental, neurological and substance use disorders worldwide. Developmental delays/disorders in young children are identified as a public health priority.[29] In the latest mhGAP intervention guide, WHO and Autism Speaks co-created and recommended that the Caregiver Skills Training (CST) programme should be widely implemented for the management of children with possible ASD symptoms, intellectual disabilities and pervasive developmental disorders, especially in low- and middle-income countries.[30] Development of the WHO-CST materials was based on the findings of several meta-analyses [27, 28, 31] and in consultation with experts and parents’ associations from all WHO regions and support from Autism Speaks.[29] The aim of the WHO-CST programme is, on the one hand, to train non-specialist social service providers such as social workers, and on the other hand, to provide caregivers whose children have ASD symptoms with a certain level of daily treatment skills to take care of their children.

The WHO-CST programme is a multi-component intervention in which the content is theoretically based on behavioural approaches promoting shared engagement and communication, such as the Joint Attention Symbolic Play Engagement Regulation, Pivotal Response Treatment and Discrete Trial Training, as
well as positive parenting approaches for promoting positive child behaviour, and/or managing challenging behaviour.[28] It consists of nine group sessions and three individual home visits and focuses on training parents to use every day play and home activities and routines as opportunities for learning and development. The programme adopts a task-shifting approach in which non-specialists, such as social workers, teachers, and community leaders, can train parents to deliver interventions for promoting their child’s development effectively. A trans-diagnostic approach is also utilised so that children who have not met the diagnostic criteria for ASD or other pervasive developmental disorders (such as developmental delays) can benefit from the programme. Under the framework of implementation science, the WHO-CST programme was in the stage of pilot-testing in more than 30 countries in 2018 [32] and several randomised controlled trials were underway in Pakistan and other countries.[33]

In the actual implementation, the WHO-CST programme consists of 12 sessions that includes nine weekly group-based sessions (each session approximately 2.5 to 3 hours’ duration) on themes such as how to engage children using play and home routines, promoting children’s communication skills, and minimising challenging behaviours. Each group of 6 to 8 caregivers is led by two facilitators who have received a 5-day training workshop conducted by WHO and Autism Speaks. In addition, three home visits (each visit approximately 1 to 1.5 hours’ duration) take place: before the first session, between sessions 4 and 5, and after the last session. These are conducted by two facilitators.

The group-based sessions deliver CST materials and focus on training caregivers to improve communication skills, behavioural skills and problem-solving ability in caring for a child with developmental delays and/or disorders and engaging in activities and routines with caregiver-child dyads. Each group session consists of key activities including an abdominal breathing exercise, group discussion and experience sharing, skills demonstration by facilitators, live practice among caregivers in pairs, and establishing plans for home practice and session review. Home visits provide an opportunity to build rapport with the family, learn about each child’s developmental competencies and behaviour and the home family environment, help the caregivers to set goals for the programme, successfully implement the strategies that have been introduced during the group sessions, troubleshoot challenges that have been encountered by caregivers, and identify any additional needs.

The JC A-Connect Family Support Team (hereinafter, the Team) was set up in August 2015 to examine the needs and the availability of services provided by NGOs
for parents of children with ASD in Hong Kong. At the beginning of 2019, the Team began to adapt and pilot the WHO-CST.

Social workers and psychologists from several NGOs and in the Team in Hong Kong received training and assessment from WHO-CST experts to be qualified to implement the HK-WHO-CST programme. These accredited master trainers are then qualified to implement the WHO-CST programme themselves and train other trainers and facilitators to implement the programme. While the trainers and facilitators instructed under these accredited master trainers were allowed to deliver the programme to parents, but they were not permitted to train other trainees. In the case of Hong Kong, all WHO-CST programme teaching materials were translated into Traditional Chinese. Lessons and guidance for the home visits were all conveyed in Cantonese, which is the colloquial language used by the major population in Hong Kong. During the COVID-19 pandemic from the beginning of 2020, all the group-based sessions were delivered by the Team via video lectures and tutorials (e.g., small group discussions) through a cloud-based peer-to-peer software platform, and the home visit session that investigated how parents interacted with their children took place in a training room situated at the University of Hong Kong.

The Present Study

This study evaluates the effectiveness of the WHO-CST through a randomised controlled trial (RCT) design in the Hong Kong-based Chinese community, and examines potential factors that hinder or promote the usefulness of the WHO-CST programme.

Participants

Caregiver-child dyads were recruited through advertisement on social media and promotion at district level through cooperating NGOs. The recruited caregiver-child dyads had to fulfil a set of inclusion criteria to be admitted into the programme. For caregivers, inclusion criteria include:

- Hong Kong residents
- Aged at least 18 years
- The primary caregiver who is responsible for the role of parenting the child. This could be the biological parent – father or mother – guardian or other adult family member (i.e., the same caregiver who will attend the WHO-CST
programme if they agree)

- Living together with the target child
- Able to communicate in Cantonese
- Able to read and write basic Traditional Chinese
- Able to stay in Hong Kong for at least six months, for home visits and nine sections of face-to-face group intervention
- Accessible by phone.

In addition, to ensure adherence to the WHO-CST programme, these caregivers agreed to the following procedures during the programme implementation:

- Agree to take their children to the university setting and attend the three home visit sessions and record videos for assessment of their interaction and communication with their children
- Agree to be recorded by a cloud-based peer-to-peer software platform in the nine group-based sessions.

For children eligible to participate the WHO-CST programme in Hong Kong:

- Between 2 and 6 years old
- Screened positive on the modified Chinese version of the checklist for autism in toddlers (C-CHAT-23) [34] or
- Suspected of displaying symptoms or behaviours of ASD or developmental delays, such as persistent deficits in social communication and social interaction across multiple contexts and restricted, repetitive patterns of behaviours, interest, or activities, or
- Suspected of displaying symptoms or behaviours of communication disorder, such as persistent difficulties in the acquisition and use of language across modalities and language abilities substantially and quantifiably below those expected for their age, or
- The above symptoms or behaviours are the primary concerns of developmental issues the child faces as reported by caregivers or clinicians (children who are suspected of co-morbid other conditions, such as intellectual disability, attention deficit hyperactivity disorder, specific learning disorder and motor disorder are also eligible if these other conditions are not primary concerns of developmental issues).
Sample Size Estimation

This protocol targets testing the clinical effect of the treatment on both rater-assessed and self-reported outcomes by caregivers of caregiver–children interaction and compare these outcomes between the intervention group and wait-list-control group. The Team assumed a conservative effect size estimate of 0.30 (i.e., moderate effect size) for the outcome measures; 80% power at 5% two-tailed significance level; and 20% attrition rate. Based on Karlsson, Engebretsen and Dainty’s [35] formula and suggestions, 130 caregiver–child dyads were proposed for recruitment. These were intended to be representative to draw significant results in the final analysis. Participating caregiver–child dyads were randomised to the intervention or to a wait-list at a 1:1 ratio: 65 caregiver–child dyads were randomly assigned to a treatment group to receive WHO-CST training while another 65 caregiver-child dyads were randomly assigned to a wait-list-control condition. As the final analysis was conducted under the intent-to-treat principle, the dropout participants were included in the analysis.

Randomised Controlled Trial Design

The caregiver–child dyad was enrolled by accredited HK-WHO-CST programme trainers and was based on the selection criteria listed above. The researcher who generated the randomised sequence for RCT was independent from the research team who recruited participants. The researcher entered caregivers’ names into a Python list (in random order, expected 130 caregivers) and used the Python function “sample()” to randomly extract 65 caregivers without replacement. The flow of the RCT design is illustrated in Figure 1. Before formally starting the HK-WHO-CST intervention, both groups completed the first assessment as the baseline for group comparison. Then, the treatment group received 12 weeks of HK-WHO-CST intervention after the screening tasks, while the wait-list-control group waited for intervention after the 12-week waiting period. The second assessment of both groups was conducted immediately after completion of the programme. To investigate the persistent effect of the intervention, a follow-up assessment was implemented 30 days after the completion of the treatment group’s intervention. In other words, the wait-list-control group took all three assessments in parallel with the treatment group and received the intervention later. Both participants in the treatment group and wait-list-control group were blind for their assignment to the RCT experiment. The whole RCT is supposed to be completed within seven months, including the intervention for
the wait-list control group.

Figure 1. Flow diagram of the study’s RCT design

Since the WHO-CST is a sustained programme and multiple-parallel training sessions have been opened continuously throughout the two years of operation, it is normal that some caregivers had waited for 3 to 6 months to receive the training. Furthermore, it is a normal practice to have multiple assessments before and during the WHO-CST sessions. The assessment, training content and practices are all identical for the treatment group and the wait-list group. Therefore, the caregivers only know that they are assigned into different training time slots, but not whether they are in the treatment group or in the wait-list-group.

Hypothesis

This study hypothesises that (1) after the intervention through the WHO-CST training, the treatment group’s caregiving knowledge and skills will be enhanced more than the wait-list-control group and (2) after the intervention, the treatment group parents’ children will misbehave less than those in the wait-list control group.

Assessment Tools

The assessment tools in this study include a parents’ self-reported online survey and video-taking of parent-children playtime in pre-set scenarios in a training room in the university setting. During the playtime, toys, duration of the playtime and instructions to parents are all standardised to minimise factors of circumstance.

Measurements in Parents’ Self-Reported Survey

Participants are invited to complete a questionnaire soliciting their sociodemographic information and their child’s characteristics for the first assessment. Then, in each assessment round, both the treatment groups and the wait-list-control groups are requested to complete the following outcome measures in the self-reported survey. All the outcome measures have been translated into Traditional Chinese.
Caregivers’ Knowledge and Skill

The Caregiver Knowledge and Skills Test is designed by the WHO-CST team and is used to assess the caregivers’ knowledge and skills related to the programme materials. Caregivers are invited to rate 24 statements on a 5-point Likert scale ranging from 1 (I strongly disagree) to 5 (I strongly agree). For example, “My child has more opportunities to learn when we are focusing attention on same toy or activity”. Further, caregivers are asked to indicate their confidence level (13 statements) on a 5-point Likert scale ranging from 1 (not confident) to 5 (very confident), such as “I feel confident in using pictures to help my child follow a routine”. Caregivers are also asked to complete three scenario-based short answer questions.

Caregivers’ Experience Using Strategies

A set of questions are used to evaluate the caregivers’ experiences with the intervention strategies that they learnt during the WHO-CST programme, in terms of their level of confidence and comfort using the strategies, as well as how difficult, effortful, and natural the caregiver perceives the strategies.[36]

Caregivers’ Quality of Life

Parents must report their quality of life in each assessment by completing the General Health Questionnaire-12 (GHQ-12). The GHQ-12 is a widely used and easy-to-understand instrument for measuring parents’ psychological strain, particularly in aspects of social dysfunction and anxiety/depression. The Chinese version of the GHQ-12 has been validated in several studies.[37,38]

Children’s Misbehaviour

Children’s suspected ASD misbehaviours are mainly gauged using two scales. The first is the Eyberg child behaviour inventory (ECBI), which is a 36-item multi-dimensional scale for parents to rate their perception of their children’s conduct problems, especially children aged 2 to 17. Parents are asked to rate how often each stated behaviour occurs on a 7-point frequency-of-occurrence scale, which generates the “intensity score”. They are also required to indicate whether the stated behaviour is still currently a problem to them, which generates the “problem score”. High scores represent a high frequency of children’s disruptive behaviour in daily life. The Chinese version of ECBI has been validated by the Education Bureau (formerly known as the Education and Manpower Bureau), Hong Kong Special. Administrative Region Government.[20]
The second scale is the Chinese version of the modified checklist for autism in toddlers (Chinese M-CHAT). This 23-item scale is a common and easy-to-administer screening tool for identification of children with autism. It addresses aspects such as children’s social relatedness, joint attention, and bringing objects to show parents. Wong et al.’s study confirms the validity of this scale on young children and its reliability for Hong Kong caregivers. [34]

**Measurements of Video-recoded Playtime**

Videos of a standardised 10-minute play scenario are taken for each of the participating parent-dyads at each assessment time (the first assessment, the second assessment and the follow-up assessment). All the videos are rated using the joint engagement rating inventory (JERI).[39] JERI was designed by experts cooperating with the WHO-CST and was targeted to characterise both child and caregiver’s activities during the communication play protocol.[40] The scale is adapted to rate a child’s engagement states as well as various aspects of the children’s and caregivers’ behaviour and their shared activities. The study’s raters must view the video records of the 10-minute play scene in the caregiver–child interaction using skills acquired in the WHO-CST training. They judge the interaction using 7-point rating scales on 10 items:

1. Unengaged
2. Joint engagement
3. Stereotyped, restricted, and repetitive behaviours
4. Attention of caregiver
5. Initiation of communication
6. Expressive language level and use
7. Scaffolding
8. Following in on child’s focus
9. Caregiver’s affection
10. Fluency and connectedness

These 10 items address various aspects of the caregiver–child interaction, including the child’s engagement state (e.g., joint engagement), child’s activities (e.g., initiation of communication), caregiver’s support of child’s activities (e.g., scaffolding), caregiver’s attention to child’s focus (e.g., following in) and dyadic interaction (e.g., fluency and connectedness).

To maintain fairness and reliability of the rating practices, the rating team are not
members of the research team. The rating team members are specifically recruited to rate the videos and have no direct contact nor interaction with any project participants. The rating team attend a distance training course, taught by WHO experts, on how to adopt the JERI to assess caregiver–child gameplay videos. There are 5 sessions (about 2 hours) in the whole training course. The trainers from WHO ensure that the raters are qualified to use JERI to rate the videos. To ensure the reliability of the coding scheme, one-third of the videos are blindly sent to two raters for rating, and inter-rater reliability of each item in the JERI is calculated.

Data Analysis

Two sources of data are collected: (1) data from the online survey platform, and (2) data collected from the JERI ratings video recording of caregiver–child interactions. For the variables that are presented as continuous or count data, the between group mean differences, the standard deviation, the range and the possible range (as provided in the instrument), are reported at different assessment time points. Given the intent-to-treat design, all caregiver–children dyads’ data are contained in the original assignment group, including those who dropped out before the end of the study, and all complete the assessment at any of the three timepoints. All the outcome measurements with continuous variables (i.e., JERI, GHQ12, ECBI) are analysed using linear mixed models (LMM) with random intercept and slope parameters, where appropriate, to examine the effect of treatment assignment (treatment group versus wait-list-control group), assessment time points (T1, T2 and T3), and their interaction on the outcome. The LMM is used because of its full information-loaded characteristic, which can involve information from all randomised (intent-to-treat) participants, including those with only partial data owing to drop out or other reasons.[41] LMM is advantageous compared to repeated measures such as ANCOVA in that they accommodate data for missing time points, hence utilise all available data, and can therefore be considered in the intent-to-treat models. The latest assessments before dropout or completion of the programme are used in the model. The assessment at T2 and its interaction with group and time is the primary interest to test our hypotheses. The LMM analysis is performed using the R package lme4 and glmmTMB.

Ethical Considerations

Before the commencement of the study, ethical approval was obtained from the Human Research Ethics Committee, the University of Hong Kong. No foreseeable
significant psychological distress or any other hazards are entailed in the study procedures.

**Plan for Obtaining Informed Consent**

Written consent is obtained from all participants before completing the baseline assessment. Participation is entirely voluntary; every participant maintains the right to withdraw from the study. The caregivers are further reassured that their participation will not affect the health care and/or social services that the families and their children are currently receiving. The text in the informed consent form is read to all potential participants (i.e., caregivers) and they have an opportunity to ask questions and express concerns (e.g., the purpose of video recording). The minimal time given to the caregivers for consideration after explanation is 15 to 20 minutes. However, the caregivers can take as much time as needed to consider taking part in the study. In addition, the caregivers are informed verbally about future publications of the study in scientific literature. Confidentiality of all information obtained is ensured.

**Anonymity and Confidentiality**

Confidentiality of all data collected is maintained and only used for research purposes. Each participant is assigned a unique identification code (ID code) that is used instead of names and thus, the identity of participants is not disclosed to unauthorised persons. Moreover, the ID codes and names are stored in separate documents from the collected data.

Data with identifiable information is kept in a locked cabinet that can only be accessed by the research team. All personal data and video-recorded files are stored in password-protected files and encrypted. No data is stored on personally owned computers or portable storage devices. No personal identifiable information is reported in any of the reports or publications.

Regarding the video records made during the home visit, facilitators upload these to an online platform developed by the information and technology professionals at the Faculty of Social Sciences of the university and only researchers have the rights to assess the online platform, which is consistently monitored by IT colleagues to protect the privacy of participants.
Role of Coordinating Team

The Family Support Team of the JC A-Connect project is subordinated the Faculty of Social Science, The University of Hong Kong. The Team is responsible for delivering the clinical services filling the syllabus and standard of WHO-CST, training trainers to deliver the WHO-CST programme at community level, collecting and analysing data for the evaluation of WHO-CST programme in Hong Kong.

Limitation

The aim of this study is to evaluate the implementation of the WHO-CST programme executed in Hong Kong during the COVID-19 period. As previously mentioned, parenting children with ASD can be extremely stressful, not only because of the role of being caregivers but also because of the stigma associated with the condition and the long wait for proper assessment to enter the health system. Due to the influence of COVID-19 and the related stringent public health measures implemented in Hong Kong, there was a possibility that the attrition rate could be impacted. Although our team expect a 20% dropout rate in the coming programme, the actual rate is unpredictable. It is possible that it could be higher than expected because of the convenience of doing it in an online environment. Our team will attempt to recruit more participants than the suggested number to prevent failure of the research study caused by the dropout problem.

Another limitation is the change in delivery mode of the WHO-CST. The original WHO-CST was designed to be delivered in a face-to-face group format. There should be three sessions of actual home visits for trainers to provide guidance on parent–child interaction in a real-life setting. Due to COVID-19, our WHO-CST were delivered online, and the home visits became sessions situated in a more controlled environment. Our evaluation results and the effect of training can only represent an “on-line delivered version” of WHO-CST that may not be applicable to the traditional face-to-face WHO-CST format.

Patient and public involvement There is no patient and public involvement in the design of this study and recruitment procedure.

Contributor’s statement P.W.C. Wong served as principal investigator of the WHO-CST programme in Hong Kong and designed this research study. S.L. Chow drafted
this protocol and revised this manuscript and is also responsible for the data management and analysis of this study. Both authors approved the publication of this protocol.

**Competing interests** The authors declare there are no competing interests.

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**Data sharing statement** This study’s data is available from August 2021. Data will be shared upon reasonable request and under the approval of the funder.

**Ethics and dissemination** This study has received the following approvals: The Human Research Ethics Committee, the University of Hong Kong (Reference number: EA1912063). Results will be made available to the public through technical reports and peer-reviewed journals.
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Recruitment

Screening

Randomization (130 Dyads)

1st Assessment for Treatment Group (65 Dyads)

Treatment Group (65 Dyads) 12 Weeks Intervention

2nd Assessment for Treatment Group

Follow-up Assessment: 30 days after the completion of the intervention

1st Assessment for Wait-list-control Group (65 Dyads)

Wait-list-control Group (65 Dyads) 12 Weeks Waiting Period

2nd Assessment for Wait-list-control Group

Follow-up Assessment: 30 days after the completion of Treatment Group's intervention

Wait-list-control Group (65 Dyads) 12 Weeks Intervention

159x241mm (72 x 72 DPI)
| Section/item          | Item No | Description                                                                                                                                                                                                 |
|----------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Administrative information |        |                                                                                                                                                                                                            |
| Title                | 1       | Implementation of WHO-CST Programme in Hong Kong: A RCT Protocol                                                                                                                                           |
| Trial registration   | 2a      | Registration Platform: Chinese Clinical Trial Registry                                                                                                                                                      |
|                      |         | Registry Name: World Health Organization Caregiver Skills Training (WHO-CST) Programme for Hong Kong Chinese families of young children with developmental delays or Autism Spectrum Disorders—Phase Three: evaluation of the pilot implementation |
|                      |         | Registration Number: ChiCTR2000034585                                                                                                                                                                        |
|                      | 2b      | All items from the World Health Organization Trial Registration Data Set                                                                                                                                     |
| Protocol version     | 3       | Date: 11th July 2020 Version: 1.02                                                                                                                                                                          |
| Funding              | 4       | The Hong Kong Jockey Club Charities Trust                                                                                                                                                                  |
| Roles and responsibilities | 5a   | Dr. Wong, Paul Wai-Ching, Department of Social Work and Social Administration, The University of Hong Kong, Project Director of WHO-CST research project in Hong Kong                                                                 |
|                      | 5b      | The Hong Kong Jockey Club Charities Trust (-852) 2966 7259                                                                                                                                              |
|                      | 5c      | The Hong Kong Jockey Club (HKJC) Charities Trust has earmarked funds to pioneer a project entitled “JC A-Connect: Jockey Club Autism Support Network” (JC A-Connect) to enhance support for children with ASD and their families and schools in Hong Kong. The WHO-CST programme is part of the “JC A-Connect” project and the HKJC Charities Trust did not involve in any design of research studies, data collection, management, analysis nor interpretation of data. The HKJC Charities Trust has the authority on the decision of releasing the final research report to the public. |
5d The Family Support Team of the JC A-Connect project is subordinated the Faculty of Social Science, The University of Hong Kong. The team is responsible for delivering the clinical services filling the syllabus and standard of WHO-CST, training trainers to deliver the WHO-CST program at community level, collecting and analyzing data for the evaluation of WHO-CST program in Hong Kong.

Introduction
Background and rationale

Developmental delays/disorders in young children are identified as a public health priority. In 2009, the World Health Organization (WHO) launched the mental health Gap Action Programme (mhGAP) aiming at bridging up the treatment gaps for mental, neurological and substance use disorders worldwide.[1] In the latest mhGAP intervention guide, WHO and Autism Speaks co-created and recommended that the Caregiver Skills Training (CST) programme should be widely implemented in the management of children with possible ASD symptoms, intellectual disabilities and pervasive developmental disorders.[2] The WHO-CST materials were developed based on findings of several meta-analyses [3, 4, 5] and in consultation with experts and parents’ association from all WHO regions and support from Autism Speaks. The aim of the WHO-CST programme is, on one hand, to train non-specialist social service providers, such as social workers and ASD children’s caregivers to let caregivers whose children having ASD symptoms acquire a certain level of daily treatment skills for taking care of their children.

This study targets to test the effectiveness of WHO-CST programme in the Hong Kong context through a randomized controlled trial. The recruited caregivers will learn a set of caregiving skills under professional guidance during the intervention. No potential mental and physical harm will be imposed to the recruited caregivers.

[1] World Health Organization. Ninth Meeting of the Mental Health Gap Action Programme (mhGAP) mhGAP Forum “Mental Health capacity building within countries” [Internet]. 2017 [cited 2021 May 7]. Available from http://www.who.int/mental_health/mhgap/forum_report_2017/en/
[2] World Health Organization. mhGAP Intervention Guide for mental, neurological and substance use disorders in non-specialized health settings [Internet]. 2016 [cited 2021 May 7]. Available from http://apps.who.int/iris/bitstream/handle/10665/250239/9789241549790-eng.pdf?sequence=1
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Although Hong Kong has a relatively advanced and well-organized public health system compared with other less developed cities, parents may still not have sufficient knowledge and information on accessing clinical professionals and services at their living districts. At the time being for parents who suspects that their children may have ASD are waiting for receiving formal diagnosis, pre-assessment intervention can be offered to enhance their caregiving skill and knowledge on handling situation of ASD children. Services or interventions which allow parents to communicate with professionals and other parents having similar caregiving experience can also moderate their anxiety, since social support and teaching parents to have positive perception can ameliorate mental and relational well-being among parents of children having ASD. Well organized pre-assessment service can also be associated with a reduced duration of diagnostic process for children. Offering adequate and relevant information in pre-assessment period can be likely to reduce total duration of the assessment process. Recent review on services prepared for ASD children also suggested that provision of pre-assessment information workshops and earlier intervention to parents can reduce their anxiety and let them become more well-prepared for formal diagnosis and services.

Furthermore, there is growing evidence supporting that enhancement in parental skills in communication, engagement and mitigating autistic mannerisms can be achieved through appropriate intervention, leading to better developmental and behavioural outcomes of ASD children, and also better family functioning. Involving parents in implementing interventions to their children allows consistent handling, and ensures that the intervention is appropriate in enhancing child’s earliest social and communicative development.

Objectives

This study hypothesizes that, (1.) after the intervention through the WHO-CST training, treatment group’s caregiving knowledge and skills will be enhanced more than the wait-list-control group and, (2.) after the intervention, the children of treatment group parents will have less misbehavior than those of the wait-list-control group parents.
The flow of the RCT design is shown in the above figure. Before formally starting the WHO-CST intervention, both groups will complete the 1st assessment as the baseline for group comparison. Then, the treatment group will receive 12 weeks of WHO-CST intervention after the screening tasks, while the wait-list-control group will wait for intervention at this 12-week waiting period. The 2nd assessment of both groups come immediately after the completion of treatment group’s intervention. To investigate the persistent effect of the intervention, a follow-up assessment will be implemented 30 days after the completion of the treatment group’s intervention. In other words, the wait-list-control group will take all the three assessments parallelly with the treatment group and will receive the intervention afterwards. Both participants in the treatment group and wait-list-control group will be blind for their assignment to the RCT experiment. The whole RCT is supposed to be completed within seven months, including the intervention to wait-list-control group.
Methods: Participants, interventions, and outcomes

Study setting 9 Under the pandemic of COVID-19, face-to-face lessons are sometimes prohibited by the government or the university. Therefore, our WHO-CST lessons will be probably delivered in the form of distanced course (e.g., by ZOOM), and some home-visits will become sessions situated in the University of Hong Kong.

Eligibility criteria 10 For caregivers, they should be:
- Hong Kong residents
- at least 18 years or above,
- the primary caregiver who is responsible for the role of parenting the child, this could be biological parent (father or mother), guardian or other adult family member (i.e., the same caregiver who will attend the WHO-CST programme if she/he agrees),
- living together with the target child,
- able to communicate in Cantonese,
- able to read and write basic Traditional Chinese, and
- able to stay in Hong Kong for at least six months for most of the time for home visits and 9 sections of face-to-face group intervention and accessible by phone.

In addition, to ensure the adherence of WHO-CST programme, these caregivers shall allow the following procedures to be carried out during the programme implementation:
- agree to take their children to the University of Hong Kong to attend the three home visit sessions and record videos for assessing their interaction and communication with their children
- agree to be recorded by ZOOM in the 9 group-based sections of intervention.

Interventions 11a In the actual implementation, the WHO-CST programme consisted of 12 sessions, which was comprised of:

11b

11c 1. 9 weekly group-based sessions (each session will last approximately for 2.5 to 3 hours), 6 to 8 caregivers in a group, led by 2 facilitators who have received a 5-day training by WHO staffs and Autism Speaks, and,

11d 2. 3 home visits (each visit will last approximately for 1 to 1.5 hours) occurred before the 1st session, between session 4 and 5, and after the last session, conducted by 2 facilitators to each caregiver’s family.
Outcomes

Participants will be invited to complete a questionnaire in soliciting their sociodemographic information and their child’s characteristics at the 1st Assessment. Then, in each round of assessment, both the treatment groups and the wait-list-control groups will be requested to complete the following outcome measures in the self-reported survey. All the outcome measures have been translated into Traditional Chinese. The outcome measurements included:

- Caregivers’ Knowledge and Skill
- Caregivers’ Experience on Using Strategies
- Caregivers’ Quality of Life
- Children’s Misbehavior
- Measurements on Video-recoded Playtime (Joint Engagement Rating Inventory (JERI))

Participant timeline

Enrolment: 12 weeks
Intervention: 12 weeks
Assessment: 1st assessment: 1 week before the start of the intervention,
2nd assessment: 1 week after the end of the intervention,
follow-up assessment: 30 days after the end of the intervention

Sample size

The Team assumes a conservative effect size estimate of 0.30 (i.e., moderate effect size) for the outcome measures, 80% power at 5% two-tailed significance level; and 10% attrition rate. Based on Karlsson, Engebretsen and Dainty’s formula and suggestions, 130 caregiver-child dyads are proposed to be recruited and should be representative to draw significant results in the final analysis. Participated caregiver-child dyads will be randomized to the intervention or to a wait list at 1:1 ratio: 65 caregiver-child dyads will be randomly assigned to a treatment group to receive WHO-CST training whereas another 65 caregiver-child dyads will be randomly assigned to a wait-list-control condition. As the final analysis will be done under the intent-to-treat principle, the dropout participants will also be included in the analysis.

Recruitment

Caregiver-child dyads as potential participants will be recruited through advertisement on social media and promotion at district level through cooperating NGOs.

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation

A researcher will put caregivers name into a Python list (in random order, expected 130 caregivers) and use the Python function “sample()” to randomly extract 65 caregivers without replacement.
Allocation concealment mechanism 16b The caregivers will be notified their allocation sequence through central telephone. They will be told not to disclose their group assessment until the start of the intervention.

Implementation 16c Researcher who generates randomized sequence for RCT is independent from the research team who recruits participant.

Blinding (masking) 17a Outcome assessors who are responsible for coding the outcome measurements are blinded throughout the whole study.

Methods: Data collection, management, and analysis

Data collection methods 18a Self-administrative questionnaire will be collected through on-line platforms. Home visit videos will be collected through video-recording app. The filled questionnaire will be double-checked by researchers and caregivers will be informed if missing data is found.

18b Researchers will also urge the caregiver to fill in the questionnaires before the deadlines.

Data management 19 All personal data and video-recorded files will be stored in password-protected files and encrypted. No data will be stored on personally-owned personal computers or portable storage devices. Data cleaning (including range checks and logical check for data value) will be proceeded after finalizing the dataset.

Statistical methods 20a Two sources of data will be collected: (1) data from the online survey platform, (2) data collected from the JERI ratings video recording caregiver-child interactions. For the variables which presented as
continuous or count data, the between group mean differences, the standard deviation, the range and the possible range (as provided in the instrument), at different time points of assessment will be reported. Given the intent-to-treat design, all caregiver-children dyads’ data will be contained in the original assignment group, including those who dropped out before the end of the study, and all will take the assessment at any of the three timepoints as possible. All the outcome measurements with continuous variables (i.e., JERI, GHQ12, ECBI, etc.) will be analyzed using linear mixed models (LMM) with random intercept and slope parameters, where appropriate, examining the effect of treatment assignment (treatment group versus wait-list-control group), time points of assessment (T1, T2 and T3), and their interaction on outcome. The reason of using the LMM is because of its full-information loaded characteristic which can involve information from all randomized (intent-to-treat) participants, including those with only partial data owing to drop-out or other reasons.[40] LMM are advantageous compared to repeated measures ANCOVA in that they accommodate data of missing time points, hence utilize all available data, and therefore can be considered in our intent-to-treat models. One’s latest assessments before dropout or completion of the programme will be used in the model. The assessment at T2 and its interaction with group and time are the primary interest to test our hypotheses. The LMM analysis will be performed by R package lme4 and glmmTMB.

Methods: Monitoring

Data monitoring 21a Data will be monitor by a senior researcher.

21b There will be no interim analyses.

Harms 22 There should be no adverse events and other unintended effects of trial interventions.

Auditing 23 For every round of assessments stated, researchers will audit the trial conduct.

Ethics and dissemination

Research ethics approval 24 Before the commencement of the study, ethical approval has already been obtained from the Human Research Ethics Committee, the University of Hong Kong.

Protocol amendments 25 This is the finalized protocol before the implementation of the study and there will be no further amendment on the protocol.

Consent or assent 26a Written consent will be obtained from all the participants before
completing the baseline assessment. The participation is entirely voluntary; every participant maintains every right to withdraw from the study. For the caregivers, they will be further reassured that their participation will not affect the health care and/or social services that the families and their children are currently receiving. The text in the Informed Consent Form will be read to all potential participants (i.e., caregivers) and they will have an opportunity to ask questions and express concerns (e.g., the purpose of video-recording). The minimal time given to the caregivers for consideration after explanation will be 15 to 20 minutes. However, the caregivers can take as much time as needed to consider taking part of the study. In addition, the caregivers will be informed verbally about future publications of the study in the scientific literature. All the information obtained will be as confidential.

Confidentiality 27 All data collected will be kept confidential and be used for research purposes only. Each participant will be assigned a unique identification code (ID code). ID codes instead of names of participants will be used and thus, identity of participants would not be disclosed to unauthorized persons. Moreover, the ID codes with names will be stored separately in documents from the collected data.

Declaration of interests 28 The authors declared none financial or other competing interests.

Access to data 29 Only the principal investigator and the senior researcher who is responsible for data cleaning, data monitoring and data analysis will have access to the final trial dataset. This access right is stated on the consent form to the caregivers.

Ancillary and post-trial care 30 There is no foreseeable significant psychological distress and any other hazards entailed by the study procedures.

Dissemination policy 31a The final findings of this study will be disseminated through public reports, peer-reviewed publication or conference launched for the WHO-CST programme.

31b

31c Public can access to the full protocol when it is published on peer-reviewed journal.

Appendices

Informed consent materials 32 The consent form is attached at the end of this checklist.

Biological specimens 33 There will be no collection of biological specimens in this study.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.
Appendices: Informed consent materials

探討「世界衞生組織親子技巧訓練課程」
對支援疑似自閉症譜系障礙或發展遲緩兒童家庭的成效研究

誠邀 閣下參加由香港大學社會科學學院黃蔚澄博士監督的研究項目 - 探討「世界衞生組織親子技巧訓練課程」對支援疑似自閉症譜系障礙或發展遲緩兒童家庭的成效。

香港大學社會科學學院「賽馬喜伴同行計劃 - 家庭支援」研究團隊與世界衞生組織和自閉症之聲 (Autism Speaks®) 合作, 推行「世界衞生組織親子技巧訓練課程」, 以協助育有疑似自閉症譜系障礙或發展遲緩兒童的香港家庭。本計劃的導師將於香港大學賽馬會教學樓開辦一共九節的親子技巧訓練課程，視乎新型冠狀病毒肺炎疫情情況及政府安排, 課程部份內容或以網上教學形式處理。

若 閣下參與這個研究計劃，將會接受由本研究團隊導師帶領一共九節的親子技巧訓練課程。課程將以小組形式舉行，約每星期一次，每次約三小時。為確保導師的質素，我們會在部份課節進行小組錄影。此外，我們會在課程開始前，中段及結束後進行最多五次家訪，每次約一個半小時。在進行家訪時，導師將會觀察家長與孩子間的互動，並直接向家長建議切合其家庭情況的溝通和交流技巧，期間導師將為 閣下和 閣下的孩子之間的互動進行約三十分鐘錄影，以了解及跟進 閣下與 貴子女的互動情況。為評估實施過程及整體計劃成效，我們會邀請 閣下完成至少十五份關於課堂及家訪的問卷。其中有兩份需時大約三十到四十五分鐘，另外十三份則每份需時大約五至十分鐘。

研究計劃過程中所有收集的資料，以及 閣下和 貴子女的錄影記錄將絕對保密及只作為研究用途，所有個人資料不會被公開，所有影片的原始檔案均會被加密及妥善儲存，且只有本計劃團隊的研究人員能夠存取。在資料分析時，閤下的姓名會以編號替代，而編號只有研究人員能識別。閤下及 貴子女的錄影記錄絕對不會公開，所有影片的原始檔案均會被加密及妥善儲存，個人資料資料會在第一份文獻出版後保留五年，並會在第一份文獻出版五年後從研究數據中移除。

參加這個計劃並沒有可預計的風險，閤下亦不會獲得任何直接利益，然而 閣下的參與能對「世界衞生組織親子技巧訓練課程」在香港推行和實施方面提供寶貴意見，是次參與純屬自願性質，閤下可隨時終止參與是項研究，有關決定將不會引致任何不良後果。如 閣下對是項研究有任何問題，請隨時提出。

如閤下對是項研究有任何查詢，請與項目經理劉少萍博士聯絡（電話:3917-5108 / 電郵地址: drjanet@hku.hk）。如您想知道更多有關研究參與者的權益，請聯絡香港大學研究操守委員會 (2241-5267)。

非常感謝 閣下有興趣參與這項研究。
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
Evaluation on the Effectiveness on the Implementation of World Health Organisation (WHO) Caregiver skills Training (CST) Programme in Hong Kong: A Randomised Controlled Trial Protocol

| Journal:       | BMJ Open                                      |
|----------------|----------------------------------------------|
| Manuscript ID  | bmjopen-2021-054099.R2                       |
| Article Type:  | Protocol                                     |
| Date Submitted by the Author: | 08-Mar-2022                  |
| Complete List of Authors: | Wong, W.C. Paul; University of Hong Kong Faculty of Social Sciences, Department of Social Work and Social Administration
 | Chow, S. L.; University of Hong Kong Faculty of Social Sciences, Department of Social Work and Social Administration |
| Primary Subject Heading: | Evidence based practice                     |
| Secondary Subject Heading: | Health services research, Paediatrics       |
| Keywords:      | PUBLIC HEALTH, Child & adolescent psychiatry < PSYCHIATRY, MENTAL HEALTH |
Evaluation on the Effectiveness on the Implementation of World Health Organisation (WHO) Caregiver skills Training (CST) Programme in Hong Kong: A Randomised Controlled Trial Protocol

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RCT Registration Meta Data

Registration Platform: Chinese Clinical Trial Registry

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Registry Name: World Health Organization Caregiver Skills Training (WHO-CST) Programme for Hong Kong Chinese families of young children with developmental delays or autism spectrum disorder – Phase Three: evaluation of the pilot implementation

Registration Number: ChiCTR2000034585

Registration Date: July 2020

Protocol Version: 1.2

Protocol Preprint: https://medrxiv.org/cgi/content/short/2021.05.17.21257327v1
Abstract

Introduction This protocol delineates the research design and analytical framework used to evaluate the effectiveness of the WHO-CST in Hong Kong. The WHO-CST aims to enhance the caregiver skills of parents of children with potential autism spectrum disorders (ASD) and/or developmental delays.

Methods and analysis In this study, 130 eligible caregiver-child dyads were recruited and randomly assigned to the experimental and wait-list control groups. A randomised controlled trial (RCT) design was adopted to compare the changes between the two groups regarding caregivers’ skills, knowledge, and practices when interacting with their children with impairments due to ASD. Assessments were conducted before, immediately after, and one month after the completion of the WHO-CST programme. The primary measurement tool was the joint engagement rating inventory (JERI) developed by WHO experts to gauge how parents engage their children. A 10-minute video recording of their dyadic interaction and behaviours in a defined play setting was used for the measurement. A set of other measurements of caregivers’ knowledge, confidence, and experience of using the caregiving skills were also measured.

Ethics and dissemination Ethics approval was received from the Human Research Ethics Committee (EA1901033), The University of Hong Kong. The final findings of this study will be disseminated through public reports, peer-reviewed publication or at a conference launched for the WHO-CST programme.

Chinese Clinical Trial Registry number: This RCT practice was registered at the Chinese Clinical Trial Registry in July 2020 (No. ChiCTR2000034585).
Strengths and Limitations

- The WHO-CST is a programme that has been piloted in over 30 cities, mainly in low- and middle-income countries; this study evaluates the effectiveness of the programme through a RCT design in a high-income and developed Chinese community (Hong Kong).
- To enhance the objectivity of the primary outcome measure, this study uses the ratings of specially trained assessors of changes in interactions between caregivers and their children.
- Under the influence of COVID-19, the programme was delivered through a cloud-based peer-to-peer software platform, while the home visits were conducted in a university setting instead due to the public health concerns.
- Participation and attrition rates may be impacted due to the change in delivery mode of the WHO-CST in Hong Kong.
Introduction

The American Psychiatric Association’s Diagnostic and Statistical Manual, Fifth Edition (DSM-5) defines autism spectrum disorder (ASD) as a condition of persistent deficits in social communication and social interaction across multiple contexts, including Asperger syndrome, pervasive developmental disorder not otherwise specified (PDD-NOS), and other similar conditions.[1] In 2016, the Autism and Developmental Disabilities Monitoring Network (ADDM) estimated the prevalence of ASD among children aged 8 years was 18.5 per 1,000 children in 11 selected states in the United States, while other recent reports from the ADDM network state that in the United States, the 4-year-old ASD prevalence and the 8-year-old ASD prevalence are 13.4 per 1,000,[2] and 16.8 per 1,000, respectively.[3] These figures have doubled when compared to those reported in 10 years ago (i.e., 6.7 per 1000).[3] A recent meta-analysis found that the pooled estimate of ASD prevalence was 0.36% in nine selected Asian countries,[3] which is significantly higher than in a similar analysis conducted in 2010 (0.15%).[1] The pooled estimate of ASD prevalence in mainland China was about 0.39% in a meta-analysis conducted in 2018.[4]

Taking care of children with ASD symptoms can be challenging, especially when they may exhibit one or more of the core and severe symptoms.[5] Many children with ASD are also found to have intellectual disabilities (intelligence quotient [IQ] ≤70),[6] or behavioural problems, such as noncompliance, aggression, and self-injury,[7] and limited capacities to acquire daily living skills. Hence, many parents have parenting issues that severely impact family functioning and psychological well-being.[8] Taking care of children with ASD may also reduce opportunities for socialisation with others and have a negative impact on relationships with spouses or partners.[9,10]

Children with ASD in Hong Kong

According to the Education Bureau, the number of students with an ASD diagnosis in mainstream public schools rose from 2,050 in 2010, to 8,710 in 2018.[11] Furthermore, 24% of 22,980 primary school students with special education needs were diagnosed as having ASD in 2018.[12] With reference to the latest figures from the Hospital Authority, the caseload of Child and Adolescent Psychiatric Services under the Hospital Authority for ASD alone increased from around 5,000 in 2011/12 to about 9,000 in 2015/16, comprising over 60% of the caseload of the services.[13] The number of children newly diagnosed with ASD in the Child Assessment Service of the Department of Health has increased close to three times from 755 in 2006 to 2,021 in 2015, while
the number of pre-schoolers with significant developmental disorders has doubled.[14] The abovementioned evidence demonstrates that the figures for children diagnosed as having ASD in Hong Kong have increased rapidly in the last two decades.

Parents of children with ASD living in Chinese society may face additional social stigma since traditional Chinese culture emphasises the association of parents’ competence with children’s academic achievement and behaviour.[15] Parents tend to internalise such external criticism of their children as affiliate stigma and assume their own responsibility for the stigmatic condition. They believe that they may be unable to control their children’s condition and corresponding stigmatisation. Such affiliate stigma brings psychological and parenting stress to the parents, and consequently damages their mental health and psychological well-being,[16-17] delays formal diagnosis due to denial of children’s ASD symptoms, and sometimes hinders their children’s involvement in community participation.[18-19]

The cost of accessing services for children with ASD symptoms through the private health system can be high for the lower class in Hong Kong if they want early diagnosis and treatment for their children.[15,20] The Hong Kong government provides free to low cost public services such as early diagnosis and medical treatment through Child Assessment Centres and non-governmental organisation (NGO) services at district levels for children under 12 years of age, but they are not sufficient to fulfil the overwhelming demands and as a result, there is a rather long waiting period (from 12 to 24 months) for initial developmental assessment.[21-22] The delay in diagnosis can have ramifications for children’s school enrolment and delay necessary treatment and services.[21] Self-stigma, anxiety, and hesitation in seeking formal diagnosis and services may also contribute to parent’s lack of awareness and knowledge of ASD and developmental delay. Although Hong Kong has a relatively advanced and well-organised public health system compared with other less developed cities, parents may not have sufficient knowledge and information about accessing clinical professionals and services in their residential districts.[23]

When parents who suspect that their children may have ASD are waiting to receive a formal diagnosis, pre-assessment intervention can be offered to enhance their caregiving skills and knowledge of early intervention. Services or interventions that allow parents to communicate with professionals and other parents with similar caregiving experiences can also moderate their anxiety since social support and teaching parents to have a positive outlook can mitigate mental and relational well-being issues.[16, 24] Offering adequate and relevant information in the pre-
assessment period can reduce the total duration of the assessment process.[25] A recent review of services prepared for children with ASD also suggests that provision of pre-assessment information packages, seminars, and earlier interventions can reduce parents’ anxiety and ensure they are better prepared for formal diagnosis and services.[23]

Furthermore, there is growing evidence that enhancement of parental skills in communication, engagement and mitigation of autistic mannerisms can be achieved through appropriate intervention, which can lead to better developmental and behavioural outcomes for ASD children and also improve family functioning.[26-27] Involving parents in implementing interventions for their children allows consistent handling and ensures that the intervention is appropriate in enhancing a child’s earliest social and communicative development in their daily living environment.[10]

The WHO-CST Programme

In 2009, World Health Organisation (WHO) launched the mental health Gap Action Programme (mhGAP). The programme aims to bridge the treatment gaps for mental, neurological and substance use disorders worldwide. Developmental delays/disorders in young children are identified as a public health priority.[28] In the latest mhGAP intervention guide, WHO and Autism Speaks co-created and recommended that the Caregiver Skills Training (CST) programme should be widely implemented for the management of children with possible ASD symptoms, intellectual disabilities and pervasive developmental disorders, especially in low- and middle-income countries.[29] Development of the WHO-CST materials was based on the findings of several meta-analyses [26, 27, 30] and in consultation with experts and parents’ associations from all WHO regions and support from Autism Speaks.[27] The aim of the WHO-CST programme is, on the one hand, to train non-specialist social service providers such as social workers, and on the other hand, to provide caregivers whose children have ASD symptoms with a certain level of daily communication and caregiving skills to take care of their children, and self-caring skills to maintain their own psychological well-being.

The WHO-CST programme is a multi-component intervention in which the content is theoretically based on behavioural approaches promoting shared engagement and communication, such as the Joint Attention Symbolic Play Engagement Regulation, Pivotal Response Treatment and Discrete Trial Training, as well as positive parenting approaches for promoting positive child behaviour, and/or managing challenging behaviour.[27] It consists of nine group sessions and three
individual home visits and focuses on training parents to use every day play and home activities and routines as opportunities for learning and development. The programme adopts a task-sharing approach in which non-specialists, such as social workers, teachers, and community leaders, can train parents to deliver interventions for promoting their child’s development effectively. A trans-diagnostic approach is also utilised so that children who have not met the diagnostic criteria for ASD or other pervasive developmental disorders (such as developmental delays) can benefit from the programme. Under the framework of implementation science, the WHO-CST programme was in the stage of pilot-testing in more than 30 countries in 2018[31] and several randomised controlled trials were underway in some countries.[32]

In the actual implementation, the WHO-CST programme consists of 12 sessions that includes nine weekly group-based sessions (each session approximately 2.5 to 3 hours’ duration) on themes such as how to engage children using play and home routines, promoting children’s communication skills, and minimising challenging behaviours. Each group of 6 to 8 caregivers is led by two facilitators who have received a 5-day training workshop and year-long supervision conducted by WHO and Autism Speaks. In addition, three home visits (each visit lasts approximately 1 to 1.5 hours) take place: before the first session, between sessions 4 and 5, and after the last session. These are conducted by two facilitators.

The group-based sessions deliver CST materials and focus on training caregivers to improve communication skills, behavioural skills and problem-solving ability in caring for a child with potential ASD and/or developmental delays and engaging in activities and routines with caregiver-child dyads. Each group session consists of key activities including an abdominal breathing exercise, group discussion and experience sharing, skills demonstration by facilitators, live practice among caregivers in pairs, and establishing plans for home practice and session review. Home visits provide an opportunity to build rapport with the family, learn about each child’s developmental competencies and behaviour and the home family environment, help the caregivers to set goals for the programme, successfully implement the strategies that have been introduced during the group sessions, troubleshoot challenges that have been encountered by caregivers, and identify any additional needs.

The JC A-Connect Family Support Team (hereinafter, the Team) was set up in August 2015 to examine the needs and the availability of services provided by NGOs for parents of children with ASD in Hong Kong. At the beginning of 2019, the Team began to adapt and pilot the WHO-CST.
Experienced social workers and psychologists from several NGOs and in the Team in Hong Kong received training and assessment from WHO-CST experts to be qualified to implement the HK-WHO-CST programme. These accredited master trainers are then qualified to implement the WHO-CST programme themselves and train other trainers and facilitators to implement the programme. While the trainers and facilitators instructed under these accredited master trainers were allowed to deliver the programme to parents, but they were not permitted to train other trainees. In the case of Hong Kong, all WHO-CST programme teaching materials were translated into Traditional Chinese. Lessons and guidance for the home visits were all conveyed in Cantonese, which is the colloquial language used by the major population in Hong Kong. During the COVID-19 pandemic from the beginning of 2020, all the group-based sessions were delivered by the Team via video lectures and tutorials (e.g., small group discussions) through a cloud-based peer-to-peer software platform, and the home visit session that investigated how parents interacted with their children took place in a training room situated at the University of Hong Kong.

The Present Study

This study evaluates the effectiveness of the WHO-CST through a randomised controlled trial (RCT) design in the Hong Kong-based Chinese community, and examines potential factors that hinder or promote the usefulness of the WHO-CST programme.

Participants

Caregiver-child dyads were recruited through advertisement on social media and promotion at district level through cooperating NGOs. The recruited caregiver-child dyads had to fulfil a set of inclusion criteria to be admitted into the programme. For caregivers, inclusion criteria include:

- Hong Kong residents
- Aged at least 18 years
- The primary caregiver who is responsible for the role of parenting the child. This could be the biological parent – father or mother – guardian or other adult family member (i.e., the same caregiver who will attend the WHO-CST programme if they agree)
- Living together with the target child
- Able to communicate in Cantonese
Able to read and write basic Traditional Chinese
Able to stay in Hong Kong for at least six months, for home visits and nine sections of face-to-face group intervention
Accessible by phone.

In addition, to ensure adherence to the WHO-CST programme, these caregivers agreed to the following procedures during the programme implementation:

- Agree to take their children to the university setting and attend the three home visit sessions and record videos for assessment of their interaction and communication with their children
- Agree to be recorded by a cloud-based peer-to-peer software platform in the nine group-based sessions.

For children eligible to participate the WHO-CST programme in Hong Kong:

- Between 2 and 6 years old
- Screened positive on the modified Chinese version of the checklist for autism in toddlers (C-CHAT-23) [33] or
- Suspected of displaying symptoms or behaviours of ASD or developmental delays, such as persistent deficits in social communication and social interaction across multiple contexts and restricted, repetitive patterns of behaviours, interest, or activities, or
- Suspected of displaying symptoms or behaviours of communication disorder, such as persistent difficulties in the acquisition and use of language across modalities and language abilities substantially and quantifiably below those expected for their age, or
- The above symptoms or behaviours are the primary concerns of developmental issues the child faces as reported by caregivers or clinicians (children who are suspected of co-occurring with other conditions, such as intellectual disability, attention deficit hyperactivity disorder, specific learning disorder and motor disorder are also eligible if these other conditions are not primary concerns of developmental issues).

**Sample Size Estimation**

This protocol targets testing the clinical effect of the treatment on both rater-assessed and self-reported outcomes by caregivers of caregiver–children interaction and compare these outcomes between the intervention group and wait-list-control group.
The Team assumed a conservative effect size estimate of 0.30 (i.e., moderate effect size) for the outcome measures; 80% power at 5% two-tailed significance level; and 20% attrition rate. Based on Karlsson, Engebretsen and Dainty’s [34] formula and suggestions, 130 caregiver–child dyads were proposed for recruitment. These were intended to be representative to draw significant results in the final analysis. Participating caregiver–child dyads were randomised to the intervention or to a waitlist at a 1:1 ratio: 65 caregiver–child dyads were randomly assigned to a treatment group to receive WHO-CST training while another 65 caregiver-child dyads were randomly assigned to a wait-list-control condition. As the final analysis was conducted under the intent-to-treat principle, the dropout participants were included in the analysis.

Randomised Controlled Trial Design

The caregiver–child dyad was enrolled by accredited WHO-CST programme trainers in Hong Kong and was based on the selection criteria listed above. The researcher who generated the randomised sequence for RCT was independent from the research team who recruited participants. The researcher entered caregivers’ names into a Python list (in random order, expected 130 caregivers) and used the Python function “sample()” to randomly extract 65 caregivers without replacement. The flow of the RCT design is illustrated in Figure 1. Before formally starting the WHO-CST intervention, both groups completed the first assessment as the baseline for group comparison. Then, the treatment group received 12 weeks of WHO-CST intervention after the screening tasks, while the wait-list-control group waited for intervention after the 12-week waiting period. The second assessment of both groups was conducted immediately after completion of the programme. To investigate the persistent effect of the intervention, a follow-up assessment was implemented 30 days after the completion of the treatment group’s intervention. In other words, the wait-list-control group took all three assessments in parallel with the treatment group and received the intervention later. Both participants in the treatment group and waitlist-control group were blind for their assignment to the RCT experiment. The whole RCT is supposed to be completed within seven months, including the completion of the programme for the wait-list control group.

Figure 1. Flow diagram of the study’s RCT design

Since the WHO-CST is a sustained programme and multiple-parallel training sessions have been opened continuously throughout the two years of operation, it is
normal that some caregivers had waited for 3 to 6 months to receive the training. Furthermore, it is a normal practice to have multiple assessments before and during the WHO-CST sessions. The assessment, training content and practices are all identical for the treatment group and the wait-list group. Therefore, the caregivers only know that they are assigned into different training time slots, but not whether they are in the treatment group or in the wait-list-group.

Hypothesis

This study hypothesises that (1) after the intervention through the WHO-CST training, the treatment group’s caregiving knowledge and skills will be enhanced more than the wait-list-control group and (2) after the intervention, the treatment group parents’ children will misbehave less than those in the wait-list control group.

Assessment Tools

The assessment tools in this study include a parents’ self-reported online survey and video-taking of parent-children playtime in pre-set scenarios in a training room in the university setting. During the playtime, toys, duration of the playtime and instructions to parents are all standardised to minimise factors of circumstance.

Measurements in Parents’ Self-Reported Survey

Participants are invited to complete a questionnaire soliciting their sociodemographic information and their child’s characteristics for the first assessment. Then, in each assessment round, both the treatment groups and the wait-list-control groups are requested to complete the following outcome measures in the self-reported survey. All the outcome measures have been translated into Traditional Chinese.

Caregivers’ Knowledge and Skill

The Caregiver Knowledge and Skills Test is designed by the WHO-CST team and is used to assess the caregivers’ knowledge and skills related to the programme materials. Caregivers are invited to rate 24 statements on a 5-point Likert scale ranging from 1 (I strongly disagree) to 5 (I strongly agree). For example, “My child has more opportunities to learn when we are focusing attention on same toy or activity”. Further, caregivers are asked to indicate their confidence level (13 statements) on a 5-point Likert scale ranging from 1 (not confident) to 5 (very confident), such as “I feel
confident in using pictures to help my child follow a routine”. Caregivers are also asked to complete three scenario-based short answer questions.

**Caregivers’ Experience Using Strategies**

A set of questions are used to evaluate the caregivers’ experiences with the intervention strategies that they learnt during the WHO-CST programme, in terms of their level of confidence and comfort using the strategies, as well as how difficult, effortful, and natural the caregiver perceives the strategies.[35]

**Caregivers’ Quality of Life**

Parents must report their quality of life in each assessment by completing the General Health Questionnaire-12 (GHQ-12). The GHQ-12 is a widely used and easy-to-understand instrument for measuring parents’ psychological strain, particularly in aspects of social dysfunction and anxiety/depression. The Chinese version of the GHQ-12 has been validated in several studies.[36,37]

**Children’s specific autistic features**

Children’s suspected specific autistic features are mainly gauged using two scales. The first is the Eyberg child behaviour inventory (ECBI), which is a 36-item multi-dimensional scale for parents to rate their perception of their children’s conduct problems, especially children aged 2 to 17. Parents are asked to rate how often each stated behaviour occurs on a 7-point frequency-of-occurrence scale, which generates the “intensity score”. They are also required to indicate whether the stated behaviour is still currently a problem to them, which generates the “problem score”. High scores represent a high frequency of children’s disruptive behaviour in daily life. The Chinese version of ECBI has been validated by the Education Bureau (formerly known as the Education and Manpower Bureau), HKSAR.[19]

The second scale is the Chinese version of the modified checklist for autism in toddlers (Chinese M-CHAT). This 23-item scale is a common and easy-to-administer screening tool for identification of children with autism. It addresses aspects such as children’s social relatedness, joint attention, and bringing objects to show parents. Wong et al.’s study confirms the validity of this scale on young children and its reliability for Hong Kong caregivers.[33]

**Measurements of Video-recoded Playtime**

Videos of a standardised 10-minute play scenario are taken for each of the
participating parent-dyads at each assessment time (the first assessment, the second assessment and the follow-up assessment). All the videos are rated using the joint engagement rating inventory (JERI).[38] JERI was designed by experts cooperating with the WHO-CST and was targeted to characterise both child and caregiver’s activities during the communication play protocol.[39] The scale is adapted to rate a child’s engagement states as well as various aspects of the children’s and caregivers’ behaviour and their shared activities. The study’s raters must view the video records of the 10-minute play scene in the caregiver–child interaction using skills acquired in the WHO-CST training. They judge the interaction using 7-point rating scales on 10 items:

1. Unengaged
2. Joint engagement
3. Stereotyped, restricted, and repetitive behaviours
4. Attention of caregiver
5. Initiation of communication
6. Expressive language level and use
7. Scaffolding
8. Following in on child’s focus
9. Caregiver’s affection
10. Fluency and connectedness

These 10 items address various aspects of the caregiver–child interaction, including the child’s engagement state (e.g., joint engagement), child’s activities (e.g., initiation of communication), caregiver’s support of child’s activities (e.g., scaffolding), caregiver’s attention to child’s focus (e.g., following in) and dyadic interaction (e.g., fluency and connectedness).

To maintain fairness and reliability of the rating practices, the rating team are not members of the research team. The rating team members are specifically recruited to rate the videos and have no direct contact nor interaction with any project participants. The rating team attend a distance training course, taught by WHO experts, on how to adopt the JERI to assess caregiver–child gameplay videos. There are 5 sessions (about 2 hours) in the whole training course. The trainers from WHO ensure that the raters are qualified to use JERI to rate the videos. To ensure the reliability of the coding scheme, one-third of the videos are blindly sent to two raters for rating, and inter-rater reliability of each item in the JERI is calculated.
Data Analysis

Two sources of data are collected: (1) data from the online survey platform, and (2) data collected from the JERI ratings video recording of caregiver–child interactions. For the variables that are presented as continuous or count data, the between group mean differences, the standard deviation, the range and the possible range (as provided in the instrument), are reported at different assessment time points. Given the intent-to-treat design, all caregiver–children dyads’ data are contained in the original assignment group, including those who dropped out before the end of the study, and all complete the assessment at any of the three timepoints. All the outcome measurements with continuous variables (i.e., JERI, GHQ12, ECBI) are analysed using linear mixed models (LMM) with random intercept and slope parameters, where appropriate, to examine the effect of treatment assignment (treatment group versus wait-list-control group), assessment time points (T1, T2 and T3), and their interaction on the outcome. The LMM is used because of its full information-loaded characteristic, which can involve information from all randomised (intent-to-treat) participants, including those with only partial data owing to drop out or other reasons.[40] LMM is advantageous compared to repeated measures such as ANCOVA in that they accommodate data for missing time points, hence utilise all available data, and can therefore be considered in the intent-to-treat models. The latest assessments before dropout or completion of the programme are used in the model. The assessment at T2 and its interaction with group and time is the primary interest to test our hypotheses. The LMM analysis is performed using the R package lme4 and glmmTMB.

Ethical Considerations

Before the commencement of the study, ethical approval was obtained from the Human Research Ethics Committee, the University of Hong Kong (EA190101033). No foreseeable significant psychological distress or any other hazards are entailed in the study procedures.

Plan for Obtaining Informed Consent

Written consent is obtained from all participants before completing the baseline assessment. Participation is entirely voluntary; every participant maintains the right to withdraw from the study. The caregivers are further reassured that their participation will not affect the health care and/or social services that the families and
their children are currently receiving. The text in the informed consent form is read to all potential participants (i.e., caregivers) and they have an opportunity to ask questions and express concerns (e.g., the purpose of video recording). The minimal time given to the caregivers for consideration after explanation is 15 to 20 minutes. However, the caregivers can take as much time as needed to consider taking part in the study. In addition, the caregivers are informed verbally about future publications of the study in scientific literature. Confidentiality of all information obtained is ensured.

Anonymity and Confidentiality

Confidentiality of all data collected is maintained and only used for research purposes. Each participant is assigned a unique identification code (ID code) that is used instead of names and thus, the identity of participants is not disclosed to unauthorised persons. Moreover, the ID codes and names are stored in separate documents from the collected data.

Data with identifiable information is kept in a locked cabinet in the research office of the JC-Aconnect team that can only be accessed by the research team. All personal data and video-recorded files are stored in password-protected files and encrypted. No data is stored on personally owned computers or portable storage devices. No personal identifiable information is reported in any of the reports or publications.

Regarding the video records made during the home visit, facilitators upload these to an online platform developed by the information and technology professionals at the Faculty of Social Sciences of the university and only researchers have the rights to assess the online platform, which is consistently monitored by IT colleagues to protect the privacy of participants.

Role of Coordinating Team

The Family Support Team of the JC A-Connect project is subordinated the Faculty of Social Science, The University of Hong Kong. The Team is responsible for delivering the clinical services filling the syllabus and standard of WHO-CST, training trainers to deliver the WHO-CST programme at community level, collecting and analysing data for the evaluation of WHO-CST programme in Hong Kong.
Limitation

The aim of this study is to evaluate the implementation of the WHO-CST programme executed in Hong Kong during the COVID-19 period. As previously mentioned, parenting children with ASD can be extremely stressful, not only because of the role of being caregivers but also because of the stigma associated with the condition and the long wait for proper assessment to enter the health system. Due to the influence of COVID-19 and the related stringent public health measures implemented in Hong Kong, there was a possibility that the attrition rate could be impacted. Although our team expect a 20% dropout rate in the coming programme, the actual rate is unpredictable. It is possible that it could be higher than expected because of the convenience of doing it in an online environment. Our team will attempt to recruit more participants than the suggested number to prevent failure of the research study caused by the dropout problem.

Another limitation is the change in delivery mode of the WHO-CST. The original WHO-CST was designed to be delivered in a face-to-face group format. There should be three sessions of actual home visits for trainers to provide guidance on parent–child interaction in a real-life setting. Due to COVID-19, our WHO-CST were delivered online, and the home visits became sessions situated in a more controlled environment. Our evaluation results and the effect of training can only represent an “on-line delivered version” of WHO-CST that may not be applicable to the traditional face-to-face WHO-CST format.

Patient and public involvement There is no patient and public involvement in the design of this study and recruitment procedure.

Contributor’s statement P.W.C. Wong served as principal investigator of the WHO-CST programme in Hong Kong and co-designed this research study with the research team. S.L. Chow drafted this protocol and revised this manuscript and is also responsible for the data management and analysis of this study. Both authors approved the publication of this protocol.

Competing interests The authors declare there are no competing interests.

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Data sharing statement This study’s data is available from August 2021. Data will be shared upon reasonable request and under the approval of the funder.

Ethics and dissemination This study has received the following approvals: The Human Research Ethics Committee, the University of Hong Kong (Reference number: EA1912063). Results will be made available to the public through technical reports and peer-reviewed journals.

Contributorship Statement Both of the stated authors fulfill the ICMJE criteria in terms of their contribution to:

1. contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. draft the work or revising it critically for important intellectual content; AND
3. the final approval of the version to be published; AND
4. agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
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| Section/item         | Item No | Description                                                                                                                                                                                                                                                                                                                                 |
|---------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Administrative info |         |                                                                                                                                                                                                                                                                                                                                            |
| Title               | 1       | Implementation of WHO-CST Programme in Hong Kong: A RCT Protocol                                                                                                                                                                                                                                                                           |
| Trial registration  | 2a      | Registration Platform: Chinese Clinical Trial Registry  
Registry Name: World Health Organization Caregiver Skills Training (WHO-CST) Programme for Hong Kong Chinese families of young children with developmental delays or Autism Spectrum Disorders– Phase Three: evaluation of the pilot implementation  
Registration Number: ChiCTR2000034585  
2b All items from the World Health Organization Trial Registration Data Set  
3 Protocol version  | 3       | Date: 11th July 2020  
Version: 1.02  
4 Funding            | 4       | The Hong Kong Jockey Club Charities Trust  
5 Roles and responsibilities | 5a      | Dr. Wong, Paul Wai-Ching, Department of Social Work and Social Administration, The University of Hong Kong, Project Director of WHO-CST research project in Hong Kong  
5b The Hong Kong Jockey Club Charities Trust  
(+852) 2966 7259  
5c The Hong Kong Jockey Club (HKJC) Charities Trust has earmarked funds to pioneer a project entitled “JC A-Connect: Jockey Club Autism Support Network” (JC A-Connect) to enhance support for children with ASD and their families and schools in Hong Kong. The WHO-CST programme is part of the “JC A-Connect” project and the HKJC Charities Trust did not involve in any design of research studies, data collection, management, analysis nor interpretation of data. The HKJC Charities Trust has the authority on the decision of releasing the final research report to the public. |
5d The Family Support Team of the JC A-Connect project is subordinated the Faculty of Social Science, The University of Hong Kong. The team is responsible for delivering the clinical services filling the syllabus and standard of WHO-CST, training trainers to deliver the WHO-CST program at community level, collecting and analyzing data for the evaluation of WHO-CST program in Hong Kong.

Introduction
Developmental delays/disorders in young children are identified as a public health priority. In 2009, the World Health Organization (WHO) launched the mental health Gap Action Programme (mhGAP) aiming at bridging up the treatment gaps for mental, neurological and substance use disorders worldwide.[1] In the latest mhGAP intervention guide, WHO and Autism Speaks co-created and recommended that the Caregiver Skills Training (CST) programme should be widely implemented in the management of children with possible ASD symptoms, intellectual disabilities and pervasive developmental disorders.[2] The WHO-CST materials were developed based on findings of several meta-analyses [3, 4, 5] and in consultation with experts and parents’ association from all WHO regions and support from Autism Speaks. The aim of the WHO-CST programme is, on one hand, to train non-specialist social service providers, such as social workers and ASD children’s caregivers to let caregivers whose children having ASD symptoms acquire a certain level of daily treatment skills for taking care of their children.

This study targets to test the effectiveness of WHO-CST programme in the Hong Kong context through a randomized controlled trial. The recruited caregivers will learn a set of caregiving skills under professional guidance during the intervention. No potential mental and physical harm will be imposed to the recruited caregivers.

[1] World Health Organization. Ninth Meeting of the Mental Health Gap Action Programme (mhGAP) mhGAP Forum “Mental Health capacity building within countries” [Internet]. 2017 [cited 2021 May 7]. Available from http://www.who.int/mental_health/mhgap/forum_report_2017/en/
[2] World Health Organization. mhGAP Intervention Guide for mental, neurological and substance use disorders in non-specialized health settings [Internet]. 2016 [cited 2021 May 7]. Available from http://apps.who.int/iris/bitstream/handle/10665/250239/9789241549790-eng.pdf?sequence=1
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[5] 30. Reichow B, Kogan C, Barbui C, Smith I, Yasamy MT, Servili C. Parent skills training for parents of children or adults with developmental disorders: systematic review and meta-analysis protocol. BMJ Open. 2014;4(8); e005799. doi:10.1136/bmjopen-2014-005799
Although Hong Kong has a relatively advanced and well-organized public health system compared with other less developed cities, parents may still not have sufficient knowledge and information on accessing clinical professionals and services at their living districts. At the time being for parents who suspects that their children may have ASD are waiting for receiving formal diagnosis, pre-assessment intervention can be offered to enhance their caregiving skill and knowledge on handling situation of ASD children. Services or interventions which allow parents to communicate with professionals and other parents having similar caregiving experience can also moderate their anxiety, since social support and teaching parents to have positive perception can ameliorate mental and relational well-being among parents of children having ASD. Well organized pre-assessment service can also be associated with a reduced duration of diagnostic process for children. Offering adequate and relevant information in pre-assessment period can be likely to reduce total duration of the assessment process. Recent review on services prepared for ASD children also suggested that provision of pre-assessment information workshops and earlier intervention to parents can reduce their anxiety and let them become more well-prepared for formal diagnosis and services.

Furthermore, there is growing evidence supporting that enhancement in parental skills in communication, engagement and mitigating autistic mannerisms can be achieved through appropriate intervention, leading to better developmental and behavioural outcomes of ASD children, and also better family functioning. Involving parents in implementing interventions to their children allows consistent handling, and ensures that the intervention is appropriate in enhancing child’s earliest social and communicative development.

Objectives This study hypothesizes that, (1.) after the intervention through the WHO-CST training, treatment group’s caregiving knowledge and skills will be enhanced more than the wait-list-control group and, (2.) after the intervention, the children of treatment group parents will have less misbehavior than those of the wait-list-control group parents.
Trial design

The flow of the RCT design is shown in the above figure. Before formally starting the WHO-CST intervention, both groups will complete the 1st assessment as the baseline for group comparison. Then, the treatment group will receive 12 weeks of WHO-CST intervention after the screening tasks, while the wait-list-control group will wait for intervention at this 12-week waiting period. The 2nd assessment of both groups come immediately after the completion of treatment group's intervention. To investigate the persistent effect of the intervention, a follow-up assessment will be implemented 30 days after the completion of the treatment group’s intervention. In other words, the wait-list-control group will take all the three assessments parallelly with the treatment group and will receive the intervention afterwards. Both participants in the treatment group and wait-list-control group will be blind for their assignment to the RCT experiment. The whole RCT is supposed to be completed within seven months, including the intervention to wait-list-control group.
Methods: Participants, interventions, and outcomes

Study setting
Under the pandemic of COVID-19, face-to-face lessons are sometimes prohibited by the government or the university. Therefore, our WHO-CST lessons will be probably delivered in the form of distanced course (e.g., by ZOOM), and some home-visits will become sessions situated in the University of Hong Kong.

Eligibility criteria
For caregivers, they should be:
- Hong Kong residents
- at least 18 years or above,
- the primary caregiver who is responsible for the role of parenting the child, this could be biological parent (father or mother), guardian or other adult family member (i.e., the same caregiver who will attend the WHO-CST programme if she/he agrees),
- living together with the target child,
- able to communicate in Cantonese,
- able to read and write basic Traditional Chinese, and
- able to stay in Hong Kong for at least six months for most of the time for home visits and 9 sections of face-to-face group intervention and accessible by phone.

In addition, to ensure the adherence of WHO-CST programme, these caregivers shall allow the following procedures to be carried out during the programme implementation:
- agree to take their children to the University of Hong Kong to attend the three home visit sessions and record videos for assessing their interaction and communication with their children
- agree to be recorded by ZOOM in the 9 group-based sections of intervention.

Interventions
In the actual implementation, the WHO-CST programme consisted of 12 sessions, which was comprised of:

1. 9 weekly group-based sessions (each session will last approximately for 2.5 to 3 hours), 6 to 8 caregivers in a group, led by 2 facilitators who have received a 5-day training by WHO staffs and Autism Speaks, and,
2. 3 home visits (each visit will last approximately for 1 to 1.5 hours) occurred before the 1st session, between session 4 and 5, and after the last session, conducted by 2 facilitators to each caregiver’s family.
Outcomes

Participants will be invited to complete a questionnaire in soliciting their sociodemographic information and their child’s characteristics at the 1st Assessment. Then, in each round of assessment, both the treatment groups and the wait-list-control groups will be requested to complete the following outcome measures in the self-reported survey. All the outcome measures have been translated into Traditional Chinese. The outcome measurements included:

- Caregivers’ Knowledge and Skill
- Caregivers’ Experience on Using Strategies
- Caregivers’ Quality of Life
- Children’s Misbehavior
- Measurements on Video-recoded Playtime (Joint Engagement Rating Inventory (JERI))

Participant timeline

Enrolment: 12 weeks
Intervention: 12 weeks
Assessment: 1st assessment: 1 week before the start of the intervention, 2nd assessment: 1 week after the end of the intervention, follow-up assessment: 30 days after the end of the intervention

Sample size

The Team assumes a conservative effect size estimate of 0.30 (i.e., moderate effect size) for the outcome measures, 80% power at 5% two-tailed significance level; and 10% attrition rate. Based on Karlsson, Engebretsen and Dainty’s formula and suggestions, 130 caregiver-child dyads are proposed to be recruited and should be representative to draw significant results in the final analysis. Participated caregiver-child dyads will be randomized to the intervention or to a wait list at 1:1 ratio: 65 caregiver-child dyads will be randomly assigned to a treatment group to receive WHO-CST training whereas another 65 caregiver-child dyads will be randomly assigned to a wait-list-control condition. As the final analysis will be done under the intent-to-treat principle, the dropout participants will also be included in the analysis.

Recruitment

Caregiver-child dyads as potential participants will be recruited through advertisement on social media and promotion at district level through cooperating NGOs.

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation

A researcher will put caregivers name into a Python list (in random order, expected 130 caregivers) and use the Python function “sample()” to randomly extract 65 caregivers without replacement.
Allocation concealment mechanism

The caregivers will be notified their allocation sequence through central telephone. They will be told not to disclose their group assessment until the start of the intervention.

Implementation

Researcher who generates randomized sequence for RCT is independent from the research team who recruits participant.

Blinding (masking)

Outcome assessors who are responsible for coding the outcome measurements are blinded throughout the whole study.

Methods: Data collection, management, and analysis

Data collection methods

Self-administrative questionnaire will be collected through on-line platforms. Home visit videos will be collected through video-recording app. The filled questionnaire will be double-checked by researchers and caregivers will be informed if missing data is found.

Researchers will also urge the caregiver to fill in the questionnaires before the deadlines.

Data management

All personal data and video-recorded files will be stored in password-protected files and encrypted. No data will be stored on personally-owned personal computers or portable storage devices. Data cleaning (including range checks and logical check for data value) will be proceeded after finalizing the dataset.

Statistical methods

Two sources of data will be collected: (1) data from the online survey platform, (2) data collected from the JERI ratings video recording caregiver-child interactions. For the variables which presented as...
continuous or count data, the between group mean differences, the
standard deviation, the range and the possible range (as provided in
the instrument), at different time points of assessment will be reported.
Given the intent-to-treat design, all caregiver-children dyads’ data will
be contained in the original assignment group, including those who
dropped out before the end of the study, and all will take the
assessment at any of the three timepoints as possible. All the
outcome measurements with continuous variables (i.e., JERI, GHQ12,
ECBI, etc.) will be analyzed using linear mixed models (LMM) with
random intercept and slope parameters, where appropriate,
examining the effect of treatment assignment (treatment group versus
wait-list-control group), time points of assessment (T1, T2 and T3),
and their interaction on outcome. The reason of using the LMM is
because of its full-information loaded characteristic which can involve
information from all randomized (intent-to-treat) participants, including
those with only partial data owing to drop-out or other reasons.[40]
LMM are advantageous compared to repeated measures ANCOVA in
that they accommodate data of missing time points, hence utilize all
available data, and therefore can be considered in our intent-to-treat
models. One’s latest assessments before dropout or completion of the
programme will be used in the model. The assessment at T2 and its
interaction with group and time are the primary interest to test our
hypotheses. The LMM analysis will be performed by R package lme4
and glmmTMB.

Methods: Monitoring

Data monitoring 21a Data will be monitor by a senior researcher.

21b There will be no interim analyses.

Harms 22 There should be no adverse events and other unintended effects of
trial interventions.

Auditing 23 For every round of assessments stated, researchers will audit the trial
conduct.

Ethics and dissemination

Research ethics approval 24 Before the commencement of the study, ethical approval has already
been obtained from the Human Research Ethics Committee, the
University of Hong Kong.

Protocol amendments 25 This is the finalized protocol before the implementation of the study
and there will be no further amendment on the protocol.

Consent or assent 26a Written consent will be obtained from all the participants before
26b completing the baseline assessment. The participation is entirely voluntary; every participant maintains every right to withdraw from the study. For the caregivers, they will be further reassured that their participation will not affect the health care and/or social services that the families and their children are currently receiving. The text in the Informed Consent Form will be read to all potential participants (i.e., caregivers) and they will have an opportunity to ask questions and express concerns (e.g., the purpose of video-recording). The minimal time given to the caregivers for consideration after explanation will be 15 to 20 minutes. However, the caregivers can take as much time as needed to consider taking part of the study. In addition, the caregivers will be informed verbally about future publications of the study in the scientific literature. All the information obtained will be as confidential.

Confidentiality 27 All data collected will be kept confidential and be used for research purposes only. Each participant will be assigned a unique identification code (ID code). ID codes instead of names of participants will be used and thus, identity of participants would not be disclosed to unauthorized persons. Moreover, the ID codes with names will be stored separately in documents from the collected data.

Declaration of interests 28 The authors declared none financial or other competing interests.

Access to data 29 Only the principal investigator and the senior researcher who is responsible for data cleaning, data monitoring and data analysis will have access to the final trial dataset. This access right is stated on the consent form to the caregivers.

Ancillary and post-trial care 30 There is no foreseeable significant psychological distress and any other hazards entailed by the study procedures.

Dissemination policy 31a The final findings of this study will be disseminated through public reports, peer-reviewed publication or conference launched for the WHO-CST programme.

31b

31c Public can access to the full protocol when it is published on peer-reviewed journal.

Appendices

Informed consent materials 32 The consent form is attached at the end of this checklist.

Biological specimens 33 There will be no collection of biological specimens in this study.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.
Appendices: Informed consent materials

香港大學社會科學學院

探討「世界衞生組織親子技巧訓練課程」
對支援疑似自閉症譜系障礙或發展遲緩兒童家庭的成效研究

誠邀 閣下參加由香港大學社會科學學院黃蔚澄博士監督的研究項目 - 探討「世界衞生組織親子技巧訓練課程」對支援疑似自閉症譜系障礙或發展遲緩兒童家庭的成效。

香港大學社會科學學院「賽馬喜伴同行計劃 - 家庭支援」研究團隊與世界衞生組織和自閉症之聲 (Autism Speaks®) 合作，推行「世界衞生組織親子技巧訓練課程」，以協助育有疑似自閉症譜系障礙或發展遲緩兒童的香港家庭。本計劃的導師將於香港大學賽馬會教學樓開班一共九節的親子技巧訓練課程，視乎新型冠狀病毒肺炎疫情情況及政府安排，課程部份內容或以網上教學形式處理。

若 閣下參與這個研究計劃，將會接受由本研究團隊導師帶領一共九節的親子技巧訓練課程。課程將以小組形式舉行，約每星期一次，每次約三小時。為確保導師的質素，我們會在部份課節進行小組錄影。此外，我們會在課程開始前，中段及結束後進行最多五次家訪，每次約一個半小時。在進行家訪時，導師將會觀察家長與孩子間的互動，並直接向家長建議切合其家庭情況的溝通和交流技巧，期間導師將為 閣下和 閣下的孩子之間的互動進行約三十分鐘錄影，以了解及跟進 閣下與 貴子女的互動情況。為評估實施過程及整體計劃成效，我們會邀請 閣下完成至少十五份關於課堂及家訪的問卷。其中有兩份需時大約三十到四十五分鐘，另外十三份則每份需時大約五至十分鐘。

研究計劃過程中所有收集的資料，以及 閣下和 貴子女的錄影記錄將絕對保密及只作為研究用途。所有個人資料不會被公開，所有影像的原始檔案均會被加密及妥善儲存，並只有本計劃團隊的研究人員能夠存取。在資料分析時， 閣下的姓名會以編號替代，而編號只有研究人員能識別。 閣下及 貴子女的錄影記錄絕對不會公開，所有影像的原始檔案均會被加密及妥善儲存。個人資料資料會在第一份文獻出版後保留五年，並會在第一份文獻出版五年後從研究數據中移除。

參加這個計劃並沒有可預計的風險， 閣下亦不會獲得任何直接利益，然而 閣下的參與能對「世界衞生組織親子技巧訓練課程」在香港推行和實施方面提供寶貴意見。是次參與純屬自願性質， 閣下可隨時終止參與是項研究，有關決定將不會引致任何不良後果。如 閣下對是項研究有任何問題，請隨時提出。

如 閣下對是項研究有任何查詢，請與項目經理劉少萍博士聯絡（電話: 3917-5108 / 電郵地址: drjanet@hku.hk）。如您想知道更多有關研究參與者的權益，請聯絡香港大學研究操守委員會（2241-5267）。

非常感謝 閣下有興趣參與這項研究。
香港大學社會科學學院

參與研究同意書

探討「世界衛生組織親子技巧訓練課程」
對支援自閉症譜系障礙或發展遲緩兒童家庭的成效

誠邀閣下參加由香港大學社會科學學院黃思恒博士監督的研究項目—探討「世界衛生組織親子技巧訓練課程」
對支援自閉症譜系障礙或發展遲緩兒童家庭的成效。

香港大學社會科學學院「賽馬會同行計劃」--家庭支援
研究團隊與世界衛生組織和自閉症之聲（Autism Speaks®）合作，推行「世界衛生組織親子技巧訓練課程」，以協助有自閉症譜系障礙或發展遲緩的香港家庭。本計劃的導師將於香港大學賽馬會教學樓開辦一九節的親子技巧訓練課程，評估新型冠狀病毒肺炎疫情下家庭問題及政府安排，課程部份內容或以網上教學形式處理。

若閣下接受這個研究計劃，將會接受本研究團隊導師帶領一九節的親子技巧訓練課程。課程將以小組形式舉行，於每星期一次，每次三小時。為確保導師的資料，我們會在部份教師進行小組錄影。此外，我們會在課程開始前，於家訪後進行最少五次家訪。每次家訪時，於家訪前，導師將會觀察家長與子女的互動，並直接向家長建議。合約家長及子?的互動，並及家長建議。合約家長及子女的情況資料及在課堂的互動，並直接向家長建議。合約家長及子女的互動，並直接向家長建議。

研究計劃過程中所有收集的資料，以及閣下和貴子女的錄影記錄將絕對保密及只作研究用途。所有個
人資料不會被公開，所有影像的原始檔案均會被加密及妥善儲存，並只有本研究團隊的研究人員能夠存取。在資料分析時，閣下和貴子女的姓名會以編碼替代，而編碼只供研究人員識別。閣下和貴子女的錄影記錄絕對不會公開，所有影像的原始檔案均會被加密及妥善儲存。個人識別資料會在第一份文獻出版後保留五年，並會在第一份文獻出版五年後從研究數據中移除。

參加這個計劃並沒有可預計的風險，閣下亦不會獲得任何利益，然而閣下參與的計劃「世界衛生組織
親子技巧訓練課程」在香港推行和實施方案提供寶貴意見，是次參與純屬自願性質。閣下可隨時終止參與是項研究，有關決定將不會對任何不良後果。閣下對是否參加研究有任何疑問，請隨時提出。

如閣下對該研究有任何查詢，請與項目經理李少均博士聯絡（電話：3917-1708；電郵：lxy@hku.hk）。如閣下有意問更多有關研究參與者的權益，請聯絡香港大學研究操守委員會（2241-5267）。

非常感謝閣下有興趣參與這項研究。

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