

Changes in Self-Efficacy in Japanese School-Age Children With and Without High Autistic Traits after the Universal Unified Prevention Program: A Single-Group Pilot Study

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1 **Changes in Self-Efficacy in Japanese School-Age Children With and Without High**
2 **Autistic Traits after the Universal Unified Prevention Program: A Single-Group Pilot**
3 **Study**

4
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31

32 **Abstract**

33 **Background:** Research has shown the efficacy of school-based programs for mental health
34 problems in children. However, few studies have focused on the strengths of children, such as
35 resilience, which is essential in preventing mental health problems. Moreover, no research
36 has investigated the effect of a universal school-based program on children with increased
37 autistic traits in mainstream classes. We examined the changes in children's self-efficacy,
38 social skills, and general mental health after the implementation of a newly developed
39 universal program, the Universal Unified Prevention Program for Diverse Disorders (Up2 -
40 D2), and whether similar changes occurred in children with and without higher autistic traits.

41 **Methods:** To assess possible changes associated with the program, questionnaires were
42 collected from 396 children (207 boys and 189 girls) aged 9-12 years old before (T1),
43 immediately after (T2), and three months after (T3) the implementation of the program.

44 **Results:** Results from a linear mixed-effects model showed a significant increase in
45 children's self-efficacy at T2 (adjusted difference 0.49, 95% CI 0.03 to 0.94; $p < 0.05$) and T3
46 (0.78, 95% CI 0.32 to 1.23; $p < 0.001$). There were also significant positive changes in social
47 skills and general mental health. Similar changes were observed in children with high autistic
48 traits. Autistic traits at T1 did not contribute to the degree of change in self-efficacy.

49 **Conclusions:** Our pilot study suggests that a universal program has the potential to promote
50 positive attitudes and mental health in both at-risk and not-at-risk children.

51

52 **Keywords:** Self-efficacy; Mental health; Children; Autistic traits; Cognitive-behavioural
53 therapy; School-based program; Main stream class

54

55

56 **Introduction**

57 Tackling children's mental health problems is an urgent global issue. It is estimated that
58 10-20% of children have one or more mental health problems (1), and these mental health
59 problems are also known to affect a wide range of outcomes in adulthood, even if the
60 problems are subthreshold (2). Given the evidence for the efficacy of preventive interventions
61 for mental health problems in children (3), schools are expected to play a role in recognizing
62 children's mental health needs and serving as a place to implement prevention programs (4).

63 School-based universal programs include all children enrolled in school, whereas
64 selective and indicated approaches target only high-risk children (5). Regarding the efficacy
65 of school-based depression prevention programs using universal or selective approaches, a
66 previous meta-analysis evaluated 32 programs and found that only the selective approach
67 resulted in a prevention effect (6). In addition, a network meta-analysis evaluating 137
68 randomized controlled trials (RCT) to reduce anxiety and depression in 4-18 year olds
69 concluded that there was insufficient evidence of their effectiveness (7). These studies,

70 however, may have drawn seemingly premature conclusions on the efficacy of interventions
71 since the benefits of school environments in promoting resilience have still not been fully
72 evaluated (8). In particular, there is a need to evaluate the potential effects of school-based
73 prevention programs in a more comprehensive manner, not just in terms of symptom
74 improvement.

75 Dray and colleagues (9) focused on the efficacy of universal school-based programs
76 that aimed to heighten resilience in individuals aged 5-18 years old. Their meta-analysis
77 evaluated effect sizes for seven outcomes (anxiety, depression, hyperactivity, behavioural
78 problems, internalizing problems, externalizing problems, and general psychological stress)
79 with data from 57 RCTs, with small effects being found for 4 of the 7 outcomes (depression,
80 internalizing problems, externalizing problems, and general psychological stress)
81 (Standardized Mean Difference; SMD = -0.08, -0.21, -0.18, -0.11) (9). Fenwick-Smith and
82 colleagues (10) selected studies, including non-randomized trials, that measured resilience or
83 related factors such as self-efficacy or coping skills as outcomes and conducted a systematic
84 review of studies of universal programs for elementary school children (aged 5-12 years old).
85 Of the 11 studies examined, 10 produced positive results in terms of student resilience and
86 related factors (10). Although prior research has thus suggested that universal programs may
87 have a beneficial effect, as yet, very few studies have assessed resilience or self-efficacy as a
88 primary outcome.

89 Ishikawa and colleagues (11) have developed a new school-based universal prevention
90 program—the *Universal Unified Prevention Program for Diverse Disorders* (Up2-D2),
91 which targets transdiagnostic mental health problems in primary and secondary school
92 students aged 8-15 years old. Specifically, the Up2-D2 is characterized by five main features:
93 1) a transdiagnostic approach, 2) a positive orientation, 3) a cartoon story, 4) a teaching plan
94 for teachers, and 5) interpersonal practice (inter-peer interactive activities), and is designed to
95 integrate common components of cognitive behaviour therapy (CBT) such as
96 psychoeducation, behavioural activation, social skills training, relaxation, cognitive
97 restructuring, graded exposure, and problem-solving. These components are modified and
98 tailored to fit a school's curriculum and educational format, allowing classroom teachers to
99 implement the program in the classroom. In relation to this, a feasibility study showed that
100 there was a tendency for children's self-efficacy to gradually increase through the program. In
101 addition, the overall fidelity of the program implemented by teachers was sufficient (76.2%)
102 with children exhibiting stable enjoyment, comprehension, attainment, and application
103 through the sessions. These findings support the idea that the program is feasible (11).

104 Considering individual differences, the effects of interventions on high-risk children
105 who have developmental disorder symptoms/traits and are enrolled in mainstream classes is
106 an important, but overlooked topic. It has been reported that the estimated prevalence of
107 autism spectrum disorder (ASD) is 1.89% in mainstream school classes (12). Furthermore,

108 previous studies have reported that additional mental health problems commonly occur in
109 children with ASD (13,14), and those with a higher level of autistic traits have a greater risk
110 of additional mental health problems (15,16). Importantly, there is some evidence that autistic
111 traits may have long-term negative effects. For example, a recent longitudinal community-
112 based study showed that emotional symptoms and peer problems in schoolchildren at age 7
113 were predicted by higher autistic traits assessed at age 5 (17). Another study found that higher
114 depressive symptoms in children with ASD and autistic traits who were 10 years old were
115 still present when they were 18 years old (18). Preventive interventions may be efficacious
116 for children both with and without a higher level of autistic traits. However, to the best of our
117 knowledge, as yet, no research has examined whether universal programs have a similar
118 impact on all children in mainstream classes, including those with higher autistic traits.

119 Given this, we designed a pilot study where the main objectives were to:

- 120 1. Evaluate behavioural changes that occur in children in terms of self-efficacy, social skills
121 and mental health outcomes when they receive the Up2-D2 program in mainstream classes.
- 122 2. Evaluate the impact of autistic traits on all outcomes after the program.
- 123 3. Determine whether individual factors such as age, autistic traits, and baseline mental
124 health influence behavioural changes in these children.

125

126 **Methods**

127 **Study design and setting**

128 This study employed a single-group pre- and post-test design. We evaluated the effect
129 of the Up2-D2 program on the self-efficacy, social skills, and general mental health of
130 children in Japanese elementary schools.

131

132 **Recruitment and participants**

133 The authors approached the local government boards of education in three prefectures
134 (Kyoto, Gifu, Saitama) in Japan to explain the study plan. All agreed to conduct the program
135 as a part of their regular curricula for 4th to 6th grade children, and 8 elementary schools were
136 nominated by them to participate in the study. The school principals agreed to their schools
137 participating after they were provided with the details of the program. The principal of each
138 school then sent a letter to all the parents of children in the 4th to 6th grades informing them
139 about the study. The parents of 396 children (a 55% response rate) in the 8 schools gave
140 written consent for their children to participate in the study.

141

142 **Procedure**

143 The intervention program was implemented by each classroom teacher once a week as a
144 part of the regular curricula from September 2016 to March 2017. Before the program began,
145 the teachers received one day of training provided by one of the authors. The teaching plans
146 and visual materials to be used in the classroom were provided to them before the training

147 started. After the training was completed, teachers were instructed to practice by themselves
148 using a training DVD that was given to them.

149 Questionnaire assessments were conducted at three time points: before the start of the
150 intervention (T1), immediately after the end of the program (T2), and 3 months after the end
151 of the intervention (T3). Children completed questionnaires during classes at T1, T2, and T3.
152 Each classroom teacher rated 10 children (5 boys, 5 girls) who were randomly chosen from
153 among those children whose parents had provided written consent according to a
154 predetermined procedure. When the parents of fewer than 10 children provided consent,
155 teachers rated all of the children for whom parents had provided consent. The completed
156 questionnaires were sent from the schools to the research team. After completing
157 questionnaires at home about their children, the parents also sent them to the research team
158 (Additional file 1).

159 The study procedures were in accordance with conventional ethical standards and
160 approved by the Ethics Committee of the National Center of Neurology and Psychiatry, Japan
161 (A2016-035). Only data that were obtained through the consent process were analysed in the
162 current study.

163

164 **Intervention**

165 The Up2-D2 was used in the current study. It consists of 12 sessions, each lasting about

166 45 minutes. The details of the program components are shown in Additional file 2.

167

168 **Intervention fidelity**

169 Eleven sessions excluding the final session (review and conclusion) were recorded using an
170 integrated chip (IC) recorder. We randomly extracted 9 sessions per school, resulting in 72
171 sessions (27.3%), for which we assessed fidelity. Trained research assistants rated recorded
172 sessions using a checklist relating to the main topics to be covered in each session. The
173 overall fidelity was on average 79.8% (SD=5.63, Range 70.2-80.7).

174

175 **Measures**

176 *Primary outcome measure*

177 *Self-Efficacy*

178 We used the self-rated General Self-Efficacy Scale for Children-Revised (GSESC-R;
179 (19)), that has been standardized for Japanese children. Factor analysis extracted two factors,
180 ‘sensitivity to failure experiences’ (9 items) and a ‘positive attitude’ (9 items) (19). The latter
181 ‘positive attitude’ factor (e.g. ‘When I make plans, I am certain I can make them work’,
182 ‘When I have something complicated to do, I will manage to achieve it’, ‘I am a self-reliant
183 person’) was used in this study. Each item is scored on a 4-point scale (range 9-36). Higher
184 scores indicate greater self-efficacy. The internal consistency of the ‘positive attitude’ factor

185 has been shown to be high (Cronbach's $\alpha=0.81$) among Japanese primary school children
186 (19). The Cronbach's α in our study was 0.77.

187

188 *Secondary outcome measures*

189 *Social skills and problem behaviours*

190 The Children's Social Skills Scale (CSSS; (20)) was used in the current study. The
191 CSSS is a teacher-rated 37-item scale consisting of 25 items that assess social skills (social
192 initiation, academic performance, self-control, peer reinforcement, and compliance) and 12
193 items that assess problem behaviours (externalizing behaviour and internalizing behaviour).
194 Each item is rated on a five-point scale with the total scale score ranging from 37 to 185.
195 Higher scores indicate that children have better social skills and engage in more favourable
196 behaviour. The CSSS has been shown to have a high degree of internal consistency
197 (Cronbach's $\alpha=0.78-0.89$) and good construct validity among Japanese elementary school
198 children (20). In this study Cronbach's $\alpha=0.95$

199

200 *General mental health*

201 Children's general mental health was assessed using the self-, parent-, and teacher-rated
202 Strengths and Difficulties Questionnaire (SDQ) (21). The SDQ consists of four difficulty
203 subscales (Emotional Symptoms, Conduct Problems, Hyperactivity/Inattention, and Peer

204 Problems) and one strength subscale, Prosocial Behaviour. Each subscale comprises 5 items
205 with each item being scored on a 3-point scale. Subscale scores range from 0 to 10, with
206 higher scores reflecting greater difficulty, while a higher prosocial subscale score indicates
207 greater positive behaviour. A total difficulties score (TDS) can be calculated by adding the
208 four difficulty subscale scores together (range 0-40). The Japanese version of the
209 questionnaire was used in this study (22).

210

211 *Autistic traits*

212 Autistic traits were assessed with the Social Responsiveness Scale (SRS; (23)), a 65-
213 item quantitative measure of autistic traits. Each item is scored on a 4-point scale with the
214 total raw score ranging from 0 to 195, with higher scores reflecting greater autistic traits. This
215 parent-rating scale has a continuous distribution in the general child population (24). To
216 examine whether the outcomes of this study differed by the degree of autistic traits, we
217 created three groups using SRS T-scores; (i) children within the normal range (the ASD-
218 Unlikely group, T-score ≤ 59), (ii) children with an increased number of autistic traits almost
219 corresponding to subthreshold ASD (the ASD-Possible group, T-score ≥ 60 and ≤ 75), and
220 (iii) children with the greatest autistic traits, corresponding to the threshold level (the ASD-
221 Probable group, T-score ≥ 76). T-scores were calculated according to a Japanese norm
222 stratified by gender (25).

223 GSESC-R, SDQ, and CSSS scores were obtained at T1, T2, and T3. SRS scores were
224 obtained only at T1.

225

226 **Data analysis**

227 Data from the three time points (T1, T2, and T3) were analysed to assess changes from
228 baseline using a linear mixed-effects model. The participants were included in the model as a
229 random effect, while time, the evaluator (child, parent, or teacher), and the time-evaluator
230 interaction were modelled as fixed effects, where the evaluator and interaction were included
231 only for the SDQ. The three ASD groups divided by their SRS T-scores were also included in
232 the above model. In these analyses, we estimated adjusted means for each level of fixed
233 effects and conducted *t*-tests for the differences in adjusted means for T1-T2 and T1-T3.

234 A second analysis used a linear mixed-effects model to determine which factors
235 contributed to the changes in the GSESC-R score from T1 to T2, and T3. The parent-rated
236 SDQ (T1), teacher-rated SDQ (T1), and CSSS (T1) were omitted from the full analysis since
237 initial analyses showed that they correlated poorly with change in the primary outcome. We
238 included participants as a random effect and time (T2, T3) as a fixed effect. Candidates for
239 fixed effects were gender, grade, autistic traits, the GSESC score (T1), and the 5 child-rated
240 SDQ subscales (T1). Variable selection was conducted with a stepwise method using a *p*-
241 value < 0.1 as a selection criterion.

242 All statistical analyses were performed using the SAS software program, version 9.4
243 (SAS Institute, Cary, NC, U.S.A) and SPSS Version 23.0 (IBM, Armonk, New York, U.S.A).

244

245 **Results**

246 **Children's characteristics at T1**

247 Table 1 shows grade and gender information of the participants. Information on the
248 primary and secondary outcomes at T1 is presented in Table 2. Complete SRS data were
249 collected for 285 children (51% male). The total raw SRS scores ranged from 2 to 97
250 (M=34.1, SD=18.0). The ASD-Unlikely group contained 84.6% of the children with
251 complete SRS data, while the corresponding figures for the ASD-Possible and ASD-Probable
252 groups were 11.9% and 3.5%, respectively.

253 [Insert Tables 1 and 2 here]

254 **Changes in outcome measures for all children and the 3 ASD groups between T1-T3**

255 *Primary outcome: Self-Efficacy*

256 We observed a significant difference in the adjusted mean change in the GSESC-R
257 between T1 and T2 for all children (adjusted difference 0.49, 95% CI 0.03 to 0.94; $p < 0.05$)
258 and between T1 and T3 (0.78, 95% CI 0.32 to 1.23; $p < 0.001$) (Table 3).

259 The estimated adjusted means of the GSESC-R using a linear mixed-effects model and
260 the results of *t*-tests for the differences in the adjusted means (T1-T2, T1-T3) among the 3

261 SRS groups are shown in Table 4 and Figure 1. For the ASD-Unlikely group, there was a
262 significant difference in the adjusted mean change in the GSESC-R score between T1 and T3
263 (0.77, 95% CI 0.19 to 1.23; $p < 0.001$). Similarly, for the ASD-Probable group, there was a
264 significant difference in the GSESC-R score between T1 and T3 (2.90, 95% CI 0.03 to 5.77;
265 $p < 0.05$). By contrast, for the ASD-Possible group, there were no significant across-time
266 changes.

267

268 *Secondary outcome: Social skills and problem behaviours (CSSS)*

269 There was a significant increase in the CSSS adjusted mean score for all children
270 between T1 and T2 (3.11, 95% CI 1.69 to 4.53; $p < 0.001$) and between T1 and T3 (3.61,
271 95% CI 2.14 to 5.08; $p < 0.001$) (Table 3).

272 Among the ASD groups (Table 4, Figure 1), there was a significant change in CSSS
273 adjusted means only for the ASD-Unlikely group between T1 and T2 (2.18, 95% CI 0.38 to
274 3.99; $p < 0.05$) and between T1 and T3 (3.17, 95% CI 1.40 to 4.94; $p < 0.001$).

275

276 *Secondary outcome: General mental health (SDQ)*

277 For the whole group there were significant differences in the adjusted mean change in
278 the self-rated SDQ TDS between T1 and T2 (-0.74, 95% CI -1.27 to -0.20; $p < 0.001$),
279 between T1 and T3 (-1.75, 95% CI -2.22 to -1.28; $p < 0.001$), and in the parent-rated SDQ

280 TDS between T1 and T3 (-0.42, 95% CI -0.82 to -0.01; $p < 0.05$) (Table 3). However, there
281 were no significant changes in the teacher-rated SDQ TDS scores.

282 There were significant improvements in each of the 4 SDQ self-rated difficulty subscale
283 scores, whereas only the Conduct Problems subscale score improved for parent ratings. In
284 contrast, there were no significant changes for any of the teacher-rated difficulty subscale
285 scores. For the Prosocial Behaviour subscale, there were significant improvements in child
286 ratings between T1 and T2, and teacher ratings between T1 and T2, and T1 and T3 (see
287 Additional file 3).

288 By ASD group, outcome changes were observed in both the ASD-Unlikely and the
289 ASD-Probable groups. For the ASD-Unlikely group, the adjusted mean of the self-rated SDQ
290 TDS improved between T1 and T3 (-2.04, 95% CI -2.65 to -1.42; $p < 0.001$) (Table 4). For
291 the ASD-Probable group, the adjusted mean of the self-rated SDQ TDS improved between T1
292 and T2 (-3.80, 95% CI -6.94 to -0.66; $p < 0.05$), and T1 and T3 (-4.60, 95% CI -7.74 to -1.46;
293 $p < 0.001$). In addition, the adjusted mean of the parent-rated SDQ TDS for the ASD-
294 Probable group improved between T1 and T3 (-2.60, 95% CI -4.95 to -0.25; $p < 0.05$), while
295 those of the teacher-rated SDQ TDS improved between T1 and T2 (-6.19, 95% CI -10.7 to -
296 1.69; $p < 0.05$) (Table 4, Figure 1). By contrast, for the ASD-Possible group, there were no
297 significant changes in the self-rated, parent-rated, or teacher-rated SDQ TDS. The results for
298 the SDQ subscales for each ASD group by different raters are shown in Additional file 4.

299 [Insert Tables 3 and 4 here]

300 **Variables associated with the changes in the primary outcome**

301 Table 5 presents the regression coefficients for the variables associated with changes
302 in the GSESC-R scores at T2 and T3 compared with T1. Grade, T1 GSESC-R, and the T1
303 child-rated Hyperactivity/Inattention SDQ subscale score predicted changes in the GSESC-R
304 (T1-T2-T3). Variables such as gender and the SRS score were not associated with across-time
305 changes in the primary outcome.

306 [Insert Tables 5 here]

307 **Discussion**

308 **Change in the primary outcome**

309 This study examined whether a school-based universal intervention program, the Up2-
310 D2, would increase children's self-efficacy as a primary outcome and improve social skills
311 and mental health as secondary outcomes. Results showed that children who received the
312 Up2-D2 program at school not only experienced a reduction in their general mental health-
313 related symptoms but also an improvement in self-efficacy and social skills immediately after
314 the program, which persisted three months later.

315 Our positive results may be related to the adaptation of the intervention to the school
316 environment including the involvement of teachers in the delivery of the program, which has
317 been pointed out as a key feature in achieving positive results in universal intervention

318 programs (10). In the present study, in order to facilitate the seamless implementation of the
319 program, we translated the program into ‘teaching plans’, created visual materials for
320 teachers to use when implementing the program in their classrooms, and set the program's
321 delivery time to coincide with the school's instructional time.

322 The use of cartoon characters and a workbook as a main feature of the Up2-D2 might
323 have provided an accessible storyline for the children, which may have made it more
324 enjoyable for them too. An earlier study that adopted a CBT-based universal program, using
325 cartoon characters, reported that resilience improved in 3rd to 4th grade children after the
326 completion of the program (26). There are similarities and differences between that study
327 (26) and ours; both used a CBT-based universal approach and had a positive impact on
328 resilience. On the other hand, Yamamoto et al.'s study (26) had a control group, their
329 participants were younger, the researchers rather than teachers implemented the program, and
330 the program was conducted in only one city. This may suggest that the Up2-D2 program
331 might be beneficial for even younger children, although these studies cannot be directly
332 compared.

333

334 **Changes in the secondary outcomes**

335 In our study, robust improvements were observed in teacher-rated social skills and self-rated
336 general mental health, which is consistent with the results of existing research. In terms of

337 social skills, a meta-analysis of school-based universal-level programs for children aged 5-18
338 by Durlak et al. (27) found a significant effect size for ‘positive social behaviour’. Another
339 meta-analysis of school-based universal-level programs focusing on ‘resilience-enhancing’
340 found a significant improvement in depression, anxiety, and general psychological stress for
341 CBT programs but not for non-CBT programs (9) for children aged 5-18. Furthermore, that
342 meta-analysis also provided evidence of an age effect; effects on anxiety and general
343 psychological stress were found only for children (aged 5-10 years old) but not for
344 adolescents (aged 11-18 years old) (9). In our study, children younger than 10 years old
345 accounted for 71% of the total sample. Thus, the positive outcome in general mental health
346 might be explained by the fact that a majority of our sample were elementary school children.

347

348 **Influence of autistic traits**

349 One of the reasons why previous studies may have found universal programs to be less
350 effective is because of what has been termed ‘the ceiling effect’ (6,28)], where the majority of
351 individuals in mainstream classes are low-risk children. Among our participants, the
352 prevalence of autistic traits was similar to that found in a previous Japanese representative
353 sample. Specifically, 3.5% of the whole sample in our study had threshold level autistic traits,
354 which corresponds closely to the figure – 3.6% – identified in a national survey of Japanese
355 schoolchildren in mainstream classes conducted by the Ministry of Education, Culture,

356 Sports, Science and Technology (29). Children with subthreshold-level autistic traits
357 comprised 11.9% of the whole sample, which is also very similar to the figure of 10.9%
358 reported in an earlier Japanese study (24). Furthermore, children with higher autistic traits
359 had lower self-efficacy and more mental health problems at baseline than children with few
360 or no traits in our study. Such an association between autistic traits and mental health
361 problems is also consistent with earlier findings from a Japanese community-based study
362 (17). Thus, we consider that for inclusive education to be successful it is essential to design
363 school-based programs that are beneficial for both high- and low-risk children.

364 Given this, the current study examined whether changes in outcomes differed across
365 groups with different levels of autistic traits using a linear mixed-effects model. The finding
366 that children with the highest level of autistic traits had improvements in self-efficacy and
367 general mental health problems similar to those of children with few or no autistic traits
368 indicates that the Up2-D2 program has the potential to promote positive attitudes and mental
369 health improvements in elementary school children regardless of their level of autistic traits.
370 To the best of our knowledge, no prior studies have examined the impact of universal
371 programs on children with autistic traits, although the effects of selective programs on
372 children with a diagnosis of autism have been extensively reported (30,31). Given the
373 seemingly high prevalence of ASD at threshold/subthreshold levels, there is likely to be a
374 lack of manpower within schools to implement selective programs for all those children with

375 higher autistic traits (12). In connection with this, our findings raise the possibility that
376 teacher-administered, classroom-wide mental health programs might be affordable and
377 helpful for children with and without autistic traits.

378 Autistic traits as measured by the SRS score were not associated with the primary
379 outcome, changes in the level of self-efficacy, during the study period. Rather, younger age,
380 lower self-efficacy, and fewer inattention/hyperactivity symptoms at baseline were associated
381 with a greater change in self-efficacy. The finding that younger children may benefit more
382 suggests that it may be preferable to start implementation of the program during middle
383 childhood, although further research is needed on the feasibility and acceptability of the
384 intervention at that age. It is also understandable that children with hyperactivity and
385 inattention symptoms may be less likely to benefit from the program. Children who are
386 hyperactive and inattentive are known to exhibit poor academic and educational outcomes
387 even if they do not have a diagnosis of ADHD (32), and need classroom-based interventions
388 (33). Indeed, children with ADHD often have comorbid ASD symptoms (34,35). It can be
389 speculated that one of the reasons why we did not find any significant changes for the group
390 with subthreshold-level autistic traits is that children in this group may be heterogeneous and
391 high levels of hyperactivity/inattention could have affected the results. Rigorous research is
392 needed in the future to identify factors related to the outcome and providing effective support
393 for these children.

394

395 Limitations

396 This study has several limitations. Regarding the study design, the sample size was
397 small given the diversity of the children, no control group was set up, and the follow-up
398 period was short. Regarding the SDQ, self-ratings were obtained from children younger than
399 11 years of age. However, the outcome changes associated with self-rated scores were in
400 parallel with those from parent-rated scores, which indicates that the results from self-rated
401 scores may be reliable. Future RCTs with a larger sample size and a longer follow-up period
402 are necessary to determine the efficacy of the universal program for high- and low-risk
403 children in mainstream classes.

404

405 Conclusions

406 The current study found that the implementation of a newly developed school-based
407 universal program in elementary school mainstream classes was associated with positive
408 changes across multiple domains, including self-efficacy, social skills, and mental health
409 problems. Furthermore, the degree of autistic traits did not affect the degree of change in self-
410 efficacy after the program. This suggests that the universal implementation of the program
411 may result in a wide range of positive benefits for both children at high- and low-risk for
412 mental health problems, although future rigorous research is needed to confirm this

413 supposition.

414

415 **Abbreviations**

416 RCT: Randomized controlled trials; SMD: Standardized Mean Difference; Up2-D2:

417 Universal Unified Prevention Program for Diverse Disorders; CBT: Cognitive behaviour

418 therapy; ASD: Autism spectrum disorder; GSESC-R: General Self-Efficacy Scale for

419 Children-Revised; CSSS: Children's Social Skills Scale; SDQ: Strengths and Difficulties

420 Questionnaire; TDS: Total difficulties score; SRS: Social Responsiveness Scale.

421 **Declarations**

422 **Ethics approval and consent to participate**

423 The study was approved by the Ethics Committee of the National Center of Neurology and

424 Psychiatry, Japan (A2016-035).

425 **Consent for publication**

426 Not applicable.

427 **Availability of data and materials**

428 The datasets generated and analysed during the current study are not publicly available but

429 are available from the corresponding author on reasonable request.

430 **Competing interests**

431 The authors declare that they have no competing interests.

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434 **Authors' contributions**

435 TO was responsible for the school management for program implementation and data
436 collection, performed the statistical analysis, and drafted the manuscript. SI participated in
437 the design of the study and organized workshops for schools. TS assisted with the drafting of
438 the manuscript. KM performed the statistical analysis. AS (b) revised and proofread the entire
439 text. AS (be) was responsible for the school management for program implementation and
440 data collection. NW and HS participated in the design of the study conception. YK designed
441 and managed the entire study. All authors critically revised the final manuscript. All authors
442 read and approved the final manuscript.

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446

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554 **Additional files**

555 Additional file 1
556 Microsoft word.docx
557 The process of data collection
558 Of all children recruited, the number of consenting children, parents, and teachers is shown.

559 Additional file 2
560 Microsoft word.docx
561 Components of the Up2-D2
562 The following table shows the contents of each session of the Up2-D2 program.

563 Additional file 3
564 Microsoft word.docx
565 Least square means and a comparison with the SDQ subscales at baseline using a linear
566 mixed-effects model
567 The following table shows least-square means and compares the SDQ subscales at baseline
568 using a linear mixed-effects model.
569

570 Additional file 4
571 Microsoft word.docx
572 An across-time comparison of the SDQ subscale scores for the 3 ASD groups using a linear
573 mixed-effects model
574 The following table shows an across-time comparison of the SDQ subscale scores for the 3
575 ASD groups using a linear mixed-effects model.

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584 Table 1 Characteristics of the study participants

Participants (N=396)			
Grade	Number (%)	Male	Female
4	280 (71)	144	136
5	73 (18)	41	32
6	43 (11)	22	21

585

Table 2 Primary and secondary outcome data at Baseline (T1) by autistic traits status

	Total (N=396)			ASD-Unlikely (N=241)			ASD-Possible (N=34)			ASD-Probable (N=10)		
	N	Mean (SD)	Range	N	Mean (SD)	Range	N	Mean (SD)	Range	N	Mean (SD)	Range
Primary Outcome												
Self-efficacy ^a	365 ^d	26.08 (4.72)	12-36	222	26.57 (4.18)	15-36	26	23.12 (5.15)	12-30	10	22.30 (5.08)	15-32
Secondary Outcome												
Social skills ^b	185 ^e	93.52 (16.92)	47-125	112	96.89 (15.90)	57-125	12	92.55 (15.10)	68-112	4	76.75 (12.42)	60-88
Mental health ^c												
Self-rated	364 ^f	11.90 (5.96)	1-32	221	11.07 (5.21)	1-30	26	14.81 (6.43)	4-28	10	19.50 (6.72)	8-32
Parent-rated	311 ^g	7.90 (5.22)	0-28	240	6.54 (4.16)	0-22	34	13.06 (4.71)	4-24	9	19.67 (4.92)	11-28
Teacher-rated	194 ^h	5.80 (6.16)	0-26	118	4.47 (5.00)	0-24	12	5.83 (5.81)	1-17	4	13.00 (5.60)	6-18

ASD: Autism Spectrum Disorder; SD: Standard Deviation

^a Assessed with the *GSESC-R* General Self-Efficacy Scale for Children-Revised

^b Assessed with the *CSSS* Children's Social Skills Scale

^c Assessed with the *SDQ* Strengths and Difficulties Questionnaire

^d There were 371 self-rated questionnaires for which informed consent was obtained, from which six with incomplete data were removed.

^e There were 194 teacher-rated questionnaires for which informed consent was obtained, from which nine with incomplete data were removed.

^f There were 371 self-rated questionnaires for which informed consent was obtained, from which seven with incomplete data were removed.

^g There were 317 parent-rated questionnaires for which informed consent was obtained, from which six with incomplete data were removed.

^h There were 194 self-rated questionnaires for which informed consent was obtained.

Table 3 Least square means and comparison with baseline data (T1) using a linear mixed-effects model

	T1		T2		p value ^d	T3		p value ^e
	Estimate	95%CI	Estimate	95%CI		Estimate	95%CI	
Primary Outcome								
Self-efficacy ^a	26.05	(25.57 - 26.54)	26.54	(26.00 - 27.08)	0.04*	26.83	(26.29 - 27.37)	< 0.01**
Secondary Outcome								
Social skills ^b	93.45	(91.02 - 95.87)	96.56	(94.24 - 98.87)	< 0.01**	97.06	(94.69 - 99.42)	< 0.01**
Mental health ^c								
Self-rated	11.95	(11.34 - 12.56)	11.21	(10.57 - 11.86)	< 0.01**	10.20	(9.56 - 10.83)	< 0.01**
Parent-rated	8.13	(7.56 - 8.69)	8.16	(7.57 - 8.74)	0.88	7.71	(7.16 - 8.26)	0.04*
Teacher-rated	5.87	(5.07 - 6.68)	6.00	(5.15 - 6.85)	0.63	5.87	(5.03 - 6.70)	0.98

^a Assessed with the *GSESC-R* General Self-Efficacy Scale for Children-Revised

^b Assessed with the *CSSS* Children's Social Skills Scale

^c Assessed with the *SDQ* Strengths and Difficulties Questionnaire

^d Comparing the T2 and baseline (T1) estimated scores

^e Comparing the T3 and baseline (T1) estimated scores

*p < .05, **p < .01

CI: confidence interval

T1: Baseline, T2: Immediately after the program finished, T3: Three months after the program finished.

Table 4 An across-time comparison of the 3 ASD groups using a linear mixed-effects model

ASD traits	T1		T2		p value ^d	T3		p value ^e	
	Estimate	95%CI	Estimate	95%CI		Estimate	95%CI		
Primary Outcome									
Self-efficacy ^a									
ASD-Unlikely	26.53	(25.98 - 27.08)	26.59	(25.96 - 27.21)	0.84	27.29	(26.64 - 27.95)	< 0.01**	
ASD-Possible	23.12	(21.04 - 25.19)	23.93	(22.02 - 25.84)	0.26	23.65	(21.71 - 25.60)	0.38	
ASD-Probable	22.30	(18.67 - 25.93)	23.90	(19.55 - 28.25)	0.14	25.20	(21.59 - 28.81)	0.04*	
Secondary Outcome									
Social skills ^b									
ASD-Unlikely	96.83	(93.84 - 99.83)	99.02	(96.26 - 101.8)	0.02*	100.00	(97.28 - 102.7)	< 0.01**	
ASD-Possible	93.03	(82.74 - 103.3)	96.31	(87.21 - 105.4)	0.07	95.38	(86.45 - 104.3)	0.38	
ASD-Probable	76.75	(56.99 - 96.51)	86.75	(59.73 - 113.8)	0.15	87.75	(65.42 - 110.1)	0.34	
Mental health ^c									
Self-rated									
ASD-Unlikely	11.11	(10.34 - 11.89)	10.55	(9.78 - 11.33)	0.07	9.08	(8.31 - 9.85)	< 0.01**	
ASD-Possible	14.69	(12.44 - 16.94)	13.28	(10.99 - 15.57)	0.14	13.04	(10.79 - 15.29)	0.07	
ASD-Probable	19.50	(14.70 - 24.30)	15.70	(10.90 - 20.50)	0.02*	14.90	(10.10 - 19.70)	< 0.01**	
Parent-rated									
ASD-Unlikely	6.54	(6.05 - 7.03)	6.44	(5.92 - 6.96)	0.66	6.14	(5.61 - 6.67)	0.07	
ASD-Possible	13.06	(11.14 - 14.98)	12.89	(10.89 - 14.90)	0.84	12.31	(10.27 - 14.34)	0.37	
ASD-Probable	19.50	(16.16 - 22.84)	19.43	(16.09 - 22.77)	0.95	16.90	(13.56 - 20.24)	0.03*	
Teacher-rated									
ASD-Unlikely	4.49	(3.62 - 5.35)	4.92	(4.05 - 5.78)	0.22	4.62	(3.76 - 5.49)	0.70	

ASD-Possible	5.26	(2.40 - 8.13)	5.96	(3.15 - 8.77)	0.54	6.73	(3.92 - 9.54)	0.21
ASD-Probable	14.36	(7.46 - 21.26)	8.17	(1.24 - 15.10)	0.02*	10.36	(3.42 - 17.29)	0.08

^a Assessed with the *GSESC-R* General Self-Efficacy Scale for Children-Revised

^b Assessed with the *CSSS* Children's Social Skills Scale

^c Assessed with the *SDQ* Strengths and Difficulties Questionnaire

^d Comparing the T2 and baseline (T1) estimated scores

^e Comparing the T3 and baseline (T1) estimated scores

* $p < .05$, ** $p < .01$

ASD: Autism Spectrum Disorder, CI: Confidence interval

T1: Baseline, T2: Immediately after the program, T3: Three months after the program finished.

Table 5 Regression coefficients associated with change
in the GSESC-R score at T2 and T3 compared to T1

	Δ GSESC-R			
	Estimate	(95% CI)	t value	p value
Intercept	17.95	(13.98 - 21.93)	8.88	< 0.01
Time (T2)	-0.41	(-0.83 - 0.00)	-1.96	0.05
Grade	-1.06	(-1.61 - -0.52)	-3.83	< 0.01
GSESC-R at T1	-0.43	(-0.52 - -0.33)	-8.97	< 0.01
Hyperactivity at T1	-0.34	(-0.53 - -0.16)	-3.60	< 0.01

GSESC-R General Self-Efficacy Scale for Children-Revised

Figure Legend:

Figure 1. Changes in the outcome measures of the 3 ASD groups

Figures

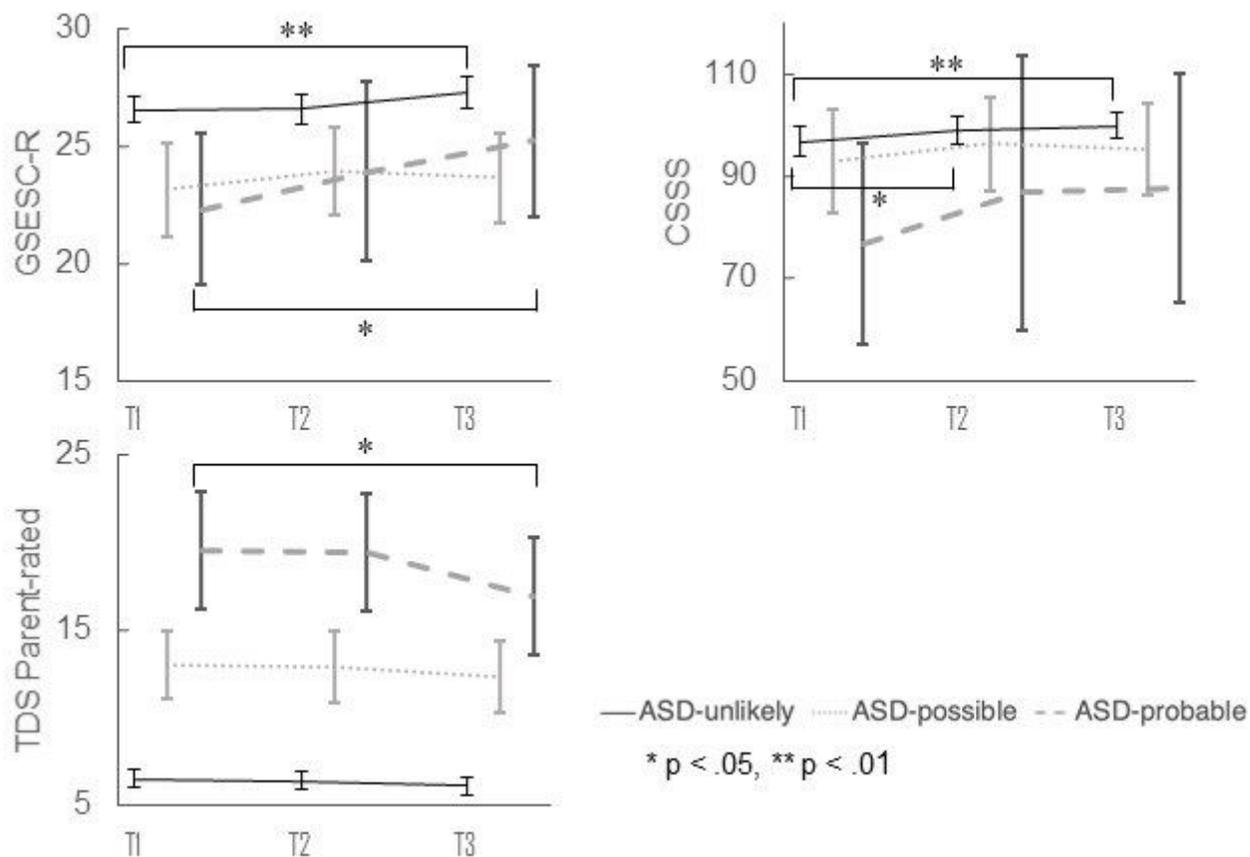


Figure 1

Changes in the outcome measures of the 3 ASD groups

Supplementary Files

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