Efficacy of acceptance and commitment therapy for people with type 2 diabetes: Systematic review and meta-analysis

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Keywords
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ABSTRACT
Aims/Introduction: This systematic review and meta-analysis aimed to investigate the efficacy and safety of acceptance and commitment therapy (ACT) for people with type 2 diabetes mellitus.

Materials and Methods: Several electronic databases were examined on 16 January 2021, including PubMed, CENTRAL, PsycINFO, International Clinical Trials Registry Platform and ClinicalTrials.gov. Randomized controlled trials were included to compare ACT with usual treatment for people with type 2 diabetes reported in any language. Primary outcome measures were glycaated hemoglobin, self-care ability assessed by the summary of diabetes self-care activities and all adverse events. The secondary outcome measure was acceptance assessed by the acceptance and action diabetes questionnaire.

Results: Of 678 publications initially identified, three trials were included in the meta-analysis. ACT resulted in a reduction in glycated hemoglobin (mean difference −0.62 points lower in the intervention group; 95% confidence interval −1.07 to −0.16; I² = 0%; low-quality evidence). In addition, ACT increased the score of the summary of diabetes self-care activities (mean difference 8.48 points higher in the intervention group; 95% confidence interval 2.16–14.80; high-quality evidence). Adverse events were not measured in all trials. ACT increased scores of the acceptance and action diabetes questionnaire (mean difference 5.98 points higher in the intervention group; 95% confidence interval 1.42–10.54; I² = 43%; low-quality evidence).

Conclusions: ACT might reduce glycated hemoglobin, and increase self-care ability and acceptance among people with type 2 diabetes.

INTRODUCTION
Type 2 diabetes mellitus is characterized by relative insulin deficiency and insulin resistance1. There are many antidiabetic medications have been approved for type 2 diabetes1. However, the efficacy of these drugs does not extend to lifestyle modification. A recent cluster randomized trial showed that significant weight loss led to remission of type 2 diabetes, affirming the need for diet and exercise therapy2. Lifestyle modification in addition to medication is important to control type 2 diabetes1.

Several types of lifestyle modification education based on the theory of behavioral change and interventions using psychotherapy have been introduced to clinical practice3. Various types of psychotherapy have been most reported to improve glycated hemoglobin (HbA1c)4. Conventional cognitive behavioral therapy...
(CBT) has been reported to be effective in lowering HbA1c. Conventional CBT focuses on reducing, changing or stopping negative thoughts and behaviors related to diabetes. However, existing CBT is often used for diabetes complicated by depression, and research on CBT evaluating self-care ability is limited. Acceptance and commitment therapy (ACT) is a promising new type of CBT. ACT is a psychological intervention that uses mindfulness, acceptance and behavior change to increase psychological flexibility, and is thought to offer more benefits than other interventions. The implementation of ACT has shown positive outcomes on a wide range of issues, including substance abuse, chronic pain, anxiety, ability to cope with depression, smoking cessation, prejudice, work stress and obsession. ACT focuses on acceptance of thoughts that emphasize values and clarity of personal goals. In other words, ACT is characterized by dealing with the issue of lifestyle rather than symptoms, whereas conventional CBT deals with the content and frequency of cognition. ACT focuses on acceptance of thoughts that emphasize values and clarity of personal goals.

No systematic review has been reported that evaluates the efficacy of ACT for diabetes mellitus. If ACT is shown to be effective for type 2 diabetes patients, it would increase treatment options. Therefore, the present study aimed to investigate the efficacy and safety of ACT for people with type 2 diabetes mellitus.

MATERIALS AND METHODS
The present study was carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement (Appendix S1). Before carrying out this study, the protocol was registered in R000042173 of the university hospital medical information (UMIN) clinical trials registry (CTR) (https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000042173).

Eligibility criteria
Type of study
All published and unpublished randomized controlled trials (RCTs), including conference abstracts and letters, were included. Cross-over studies, cluster randomized studies, quasi-studies and non-randomized trials were excluded. Studies in any country and in any language were eligible for screening. Studies were included regardless of the follow-up period.

Participants
Participants were people with type 2 diabetes aged ≥18 years diagnosed with a standard diagnostic system, such as the global guideline for type 2 diabetes. Sex, race and environment were not considered. People with gestational diabetes and people with elevated blood glucose levels that could not be diagnosed using standard diagnostic systems were excluded.

Interventions
The intervention considered was the implementation of ACT. The present study included trials regardless of the number of times, timing and the executors. The control group was usual care for type 2 diabetes.

Outcome measures
The primary outcomes measures were as follows:
1. HbA1c
HbA1c measures the number of glucose molecules bound to hemoglobin and is a percentage of the average blood glucose level over the past 2–3 months in a single blood draw. It is often used in diabetes research.
2. Self-care ability
Self-care was defined as the practice of various activities that individuals initiate and carry out on their own to maintain life and health. Self-care ability was measured using the summary of diabetes self-care activities (SDSCA) at the end of trial. SDSCA is a self-report instrument for measuring levels of self-management in people with diabetes. This instrument assesses seven aspects of the diabetes regimen: general diet, specific diet, exercise, medication taking, blood-glucose testing, foot care and smoking. Respondents report on the frequency of these self-management strategies over the previous 7 days (except smoking). This instrument has adequate validity and reliability.
3. All adverse events (AEs)
The definitions provided by the original study authors were followed.

Secondary outcomes were as follows:
1. Acceptance
Acceptance was defined as willingness to remain in contact with and actively experience particular private experiences. Acceptance was measured using the acceptance and action diabetes question (AADQ) at the end of trial. AADQ is an 11-item self-report measured on a 7-point Likert scale. The instrument measures acceptance of diabetes-related thoughts. This instrument has adequate validity and reliability.
2. Search methods for study identification
The assessment period for post-intervention HbA1c, SDSCA, AEs and AADQ was within 3–6 months after the intervention, or within 3 months after the intervention if assessed at a different time point.

Electronic search
Several electronic databases were searched on 7 June 2019 to identify relevant studies. The electronic search was updated on 16 January 2021. The following databases were searched:
1. The Cochrane Central Register of Controlled Trials (CENTRAL)
2. MEDLINE (PubMed)
3. Embase (Dialog)
4. PsycINFO (PsycNET)
Searching for other resources
To identify completed, but unpublished, included trials and to investigate reporting bias, the following registries were also searched:

1. World Health Organization International Clinical Trials Registry Platform
2. ClinicalTrials.gov

The keywords searched were ‘diabetes,’ ‘diabetes mellitus,’ and ‘acceptance and commitment therapy,’ concatenated using Boolean operators (AND/OR; Appendix S2).

In addition, clinical guidelines and related guidelines for the treatment of diabetes, as well as references to clinical guidelines and related guidelines for the treatment of diabetes were manually searched.

Authors were contacted if the required information was not available for the studies.

Data collection
Study selection
Three of six authors (TH, RS, YM, AY, JO and YO) independently checked the titles and abstracts of articles found in the
search. Eligibility was assessed based on full text review independently. Disagreements were resolved by discussion. If necessary, another reviewer (YK) acted as an arbiter. The process is summarized in the PRISMA flow chart (Figure 1).

**Data extraction and management**

Data extraction was carried out according to the pre-specified form. Three of six authors (TH, RS, YM, AY, JO, and YO) extracted data independently. For studies for which sufficient information was not available, the authors were contacted. Disagreements were resolved through discussion. If necessary, another reviewer (YK) acted as an arbiter.

**Assessment of the risk of bias in the included studies**

Three of six authors (TH, RS, YM, AY, JO and YO) independently assessed the risk of bias in the included studies using the Cochrane Risk of Bias Tool. Disagreements regarding risk of bias assessment were discussed and resolved. Domains were assessed as high risk, low risk and unclear.

**Statistical analysis**

**Measurement of treatment effect**

For continuous outcomes (HbA1c, SDSCA, AADQ), mean differences (MD) and 95% confidence intervals (CIs) were calculated. AEs were summarized according to study-specific definitions, but were not pooled.

**Assessment of heterogeneity**

First, heterogeneity was assessed by visually inspecting the forest plot. $I^2$ statistics were calculated and analyzed according to the recommendations of the Cochrane Handbook (0–40%, may be insignificant; 30–60%, may show moderate heterogeneity; 50–90%, may show considerable heterogeneity; 75–100%, may show considerable heterogeneity)\(^{19}\). $P$-values of <0.10 were considered statistically significant.

**Meta-analysis**

The data were pooled using a random effects model. The DerSimonian and Laird method was used for random effects meta-analysis\(^{20}\). All analyses were carried out using Review Manager\(^{21}\).

**Certainty of evidence**

The main results are presented in Table 1. Certainty of evidence was rated for each outcome pre-specified in the protocol following the grading of recommendations, assessment, development and evaluation (GRADE) approach\(^{22}\).

**Difference between protocol and review**

The present study did not proceed with any pre-planned subgroup analysis and sensitivity analysis due to insufficient data.

**RESULTS**

After removing duplicates, a total of 678 records were identified. A total of 13 full-text articles were qualified and five RCTs were included in the qualitative synthesis (Appendix S3). However, just three trials were included in the meta-analysis, as the outcomes of two studies were unclear. Table 2 summarizes the published studies that were included in the quantitative synthesis. The risk of bias for the quantitative synthesis is shown in Figure 2a,b.

### Primary outcome

**HbA1c**

A meta-analysis was carried out by summarizing data from three RCTs\(^{12,23,24}\) that measured HbA1c (Figure 3a). The evidence suggested that ACT resulted in a reduction in HbA1c (MD $-0.62$ points lower in the intervention group; 95% CI $-1.07$ to $-0.16$; $I^2 = 0$%; low-quality evidence). The standard deviation was not presented in one trial and was substituted in another trial (Table 1).

**Self-care ability (SDSCA)**

A meta-analysis was carried out by summarizing data from one RCT\(^{23}\) that measured SDSCA (Figure 3b). ACT increased SDSCA (MD 8.48 points higher in the intervention group; 95% CI 2.16–14.80; high-quality evidence; Table 1).

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**Table 1 | Summary of findings**

| Outcomes      | Anticipated absolute effects† (95% CI) | Relative effect (95% CI) | No. participants (studies) | Quality of the evidence (GRADE) |
|---------------|----------------------------------------|--------------------------|----------------------------|---------------------------------|
| HbA1c         | Mean HbA1c change ranged from 7.81 to 8.07 | MD $-0.62$ lower ($-1.07$ lower to $-0.16$ lower) | –                          | 232 (3 RCTs)                   | ⋁⋁⋁⋁ LOW\(^2\)                   |
| SDSCA         | Mean SDSCA change was 54.08   | MD 8.48 higher (2.16 higher to 148 higher) | –                          | 100 (1 RCTs)                   | ⋁⋁⋁ HIGH                       |
| AADQ          | Mean AADQ change ranged from 48.43 to 76.42 | MD 5.98 higher (1.42 higher to 10.54 higher) | –                          | 231 (3 RCTs)                   | ⋁⋁⋁ LOW\(^2,4,8\)              |

AADQ, acceptance and action diabetes questionnaire; CI, confidence interval; HbA1c, glycated hemoglobin; MD, mean difference; SDSCA, summary of diabetes self-care activities. †The risk in the intervention group (and its 95% confidence interval) was based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). §Participants were not blinded. ‡The intervention methods were complex.
AEs

AEs were not measured in all studies.

Secondary outcomes

Acceptance (AADQ)

A meta-analysis was carried out by combining data from three RCTs that measured the AADQ (Figure 3c). The evidence suggested that ACT resulted in an increase in AADQ (MD 5.98 points higher in the intervention group; 95% CI 1.42–10.54; \( I^2 = 43\% \); low-quality evidence; Table 1).

DISCUSSION

This is the first systematic review and meta-analysis of the use of ACT for people with type 2 diabetes. The results suggested that ACT might reduce \( \text{HbA}_{1c} \) and increase self-care ability and acceptance of people with type 2 diabetes. However, detailed results on adverse events were not available.

The first finding of the present study was that ACT significantly reduced \( \text{HbA}_{1c} \) compared with the control (MD –0.62). A systematic review of 70 RCTs of self-management training for type 2 diabetes reported a mean reduction in \( \text{HbA}_{1c} \) of 0.19, whereas another systematic review of conventional CBT
reported a mean reduction of 0.22 in HbA1c (up to 4 months)\textsuperscript{26}. In addition, a change of $>0.5$ on HbA1c decreased major cardiovascular events\textsuperscript{27}. Therefore, the efficacy of ACT on HbA1c was considered sufficiently large.

A systematic review of exercise therapy reported a 0.67\% reduction in HbA1c after $\geq 12$ weeks of exercise\textsuperscript{28}, suggesting that ACT might have an equivalent effect to this therapy.

The second finding was that ACT had an effect equivalent to increasing SDSCA scores. With the exception of one trial included in the present study, there were no trials of psychotherapy interventions for changes in SDSCA among people with type 2 diabetes. An information technology-based care management program was reported to improve SDSCA scores compared with controls in people with type 2 diabetes\textsuperscript{29}. However, this program included 24 telephone-monitoring sessions every 2 weeks for 6 months, and once a month for the remainder of the intervention period. Compared with this program, ACT might be less burdensome for people with diabetes and healthcare providers.

The third finding was that ACT might be effective for increasing scores on the AADQ. Aside from the trials included in the present study, there were no trials of interventions to change the AADQ among people with type 2 diabetes. As a general intervention, diabetes education is important as a means of promoting acceptance and change\textsuperscript{30}. However, a significant proportion of people with diabetes do not participate in diabetes education due to timing, cost and existing comorbidities\textsuperscript{31}. Compared with diabetes education, ACT intervention in the included trials contained only one session. Therefore, the likelihood of participation in ACT might be higher compared with diabetes education.

The reviewed trials did not report any AEs, although AEs were one of the primary outcomes found in the meta-analysis.
Detailed reporting of AEs occurring in clinical trials is necessary to provide all stakeholders with useful and comprehensive information on safety profiles. Therefore, future trials should be carried out with a view to thoroughly investigate AEs.

This study presented the first systematic review of RCTs that have carried out ACTs for people with diabetes. In addition, this was the first systematic review using the AADQ as an acceptance scale.

The present study had some limitations. First, most of the trials extracted through the systematic review had a small sample size. In addition, the extracted papers had a low quality of evidence. Studies with high quality of designs and large sample sizes are warranted in the future. Second, although the search was carried out to detect studies in any language, only English databases were utilized. Databases in other countries and in languages other than English were beyond the scope of the present study. Third, this study assessed the short-term efficacy of ACT. Therefore, long-term efficacy of ACT should be assessed in future studies. Finally, as this study focused on type 2 diabetes, the results cannot be generalized to type 1 diabetes.

In conclusion, the findings suggest that ACT might reduce HbA1c, improve self-care ability and enhance acceptance among people with type 2 diabetes.

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DISCLOSURE
The authors declare no conflict of interest.

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**SUPPORTING INFORMATION**

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Appendix S1 |** Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 checklist.

**Appendix S2 |** Search strategy.

**Appendix S3 |** Reasons for exclusion from eight studies.