Impact of gamification on glycaemic control among patients with type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials

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Aims

The prevalence of type 2 diabetes mellitus (T2DM) is very high and still rising. Optimal medical therapy and lifestyle management are essential in reducing the long-term complications of T2DM. Gamification, which is the use of design elements, and characteristics of games in a non-gaming context, is an innovative approach to improve healthy behaviour. It thereby could be able to improve glycaemic control in T2DM. The aim of this systematic review and meta-analysis is to evaluate the effect of gamification on glycaemic control expressed by haemoglobin A1c (HbA1c) levels in T2DM patients.

Methods and results

All articles from 2000 to 2021 were searched in electronic databases (PubMed, Cochrane Library, Embase). The total number of patients was 704. The rate of male participants and their mean ages ranged, respectively, from 46% to 94% and 60 to 63 years. Inclusion criteria were randomized controlled trials of T2DM management using gamification which included HbA1c as an outcome measure. A meta-analysis was performed. After removing duplicates, 129 articles were screened and a total of 3 articles corresponding to the inclusion criteria were identified. Haemoglobin A1c was significantly reduced [mean difference -0.21; 95% confidence interval (-0.37 to -0.05); \( P = 0.01; I^2 = 0\% \)] in the intervention group using gamification as compared to the control group.

Conclusion

Gamification has a positive effect on glycaemic control expressed by HbA1c changes in patients with T2DM. However, only three studies were included in this review. More research is needed to confirm the effectiveness of gamification in T2DM.

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Keywords
Gamification • Secondary prevention • Type 2 diabetes mellitus • Randomized controlled trial

Introduction
Type 2 diabetes mellitus (T2DM) is associated with multiple long-term complications and prolonged periods of elevated haemoglobin A1c (HbA1c) are related to increased mortality risk. Therefore, the chronic management of T2DM is extremely important. Central to the management of T2DM is the optimization of medical therapy and lifestyle management. Increasing physical activity in daily life is one of the most fundamental ways to treat and prevent T2DM and its complications.

Gamification is an emerging and innovative field within digital health. It is defined as the use of design elements and characteristic of games in non-game contexts such as healthcare. Only recently has its potential in encouraging lifestyle changes in a medical context been studied. A meta-analysis published in 2020 revealed a positive effect of augmented reality for physical activity, in which the mean age of subjects ranged from under 10 to 60 years old. The development and implementation of digital health is a rapidly emerging field in medicine. A recent systematic review reported positive impacts of telehealth interventions as self-management methods for diabetes control. A recent consensus report emphasized the enormous potential of diabetes digital technology, while also bringing to light the current lack of evidence leading to poor legal regulations. Another paper demonstrated that a mobile virtual reality (VR) technology could be used as an intervention method for health promotion of gestational diabetes. The term ‘digital health’ covers a broad spectrum of contents such as cardiac rehabilitation with activity trackers, telemonitoring, smartphone applications, VR, etc. Gamification is one of the important methodologies of ‘digital health’.

Although gamification has been shown to have positive effects on stroke patients and elderly patients in general, there is little evidence of the role of gamification for T2DM patients. The purpose of this systematic review and meta-analysis is to summarize the available data on the efficacy of gamification on glycaemic control expressed by HbA1c changes.

Methods
Data sources and search
The search was conducted in adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) reporting guideline. PubMed, Cochrane Library, and Embase databases were searched for studies published between 2000 and October 2020. The search was performed iteratively for synonyms of ‘T2DM’, ‘gamification’, and ‘HbA1c, fasting blood glucose, or exercise’ by controlled vocabulary (like MeSH or Emtree) and free text words (Supplementary material online, Figure S1). The term ‘exercise’ was chosen as it was thought to be important as a mediator of the relationship between gamification and glycaemic control. Only randomized controlled trials (RCTs) with an adult study population were included. The reference lists and referred articles of the identified relevant papers including reviews were cross-checked for additional references.

Study selection
This review included full-length research papers published in peer-reviewed journals. Inclusion criteria for studies were as follows: (i) describing an RCT; (ii) patients were diagnosed with T2DM; (iii) comparing the group using the intervention (which mainly includes gamification).
with the group not using gamification; and (iv) describing HbA1c comparing before and after the intervention.

Two investigators (T.K. and V.I.-G.) checked all identified articles on their titles and abstracts. All duplicates were excluded. If there was doubt about eligibility, articles were read in full. A third investigator (M.S.) resolved differences in decision-making. The selection procedure was conducted according to the PRISMA guideline.11

Data extraction
For each selected RCT, the first physician (T.K.) completed the data extraction. It included authors, year of publication, country of trial, number of patients including their characteristics, their achievement rate of RCT, and details of drop-out. Moreover, the kind of the gamification used, study periods and the type of the intervention and the content of the control group were extracted. The corresponding authors of selected papers were contacted for completion of missing information. One author gave additional information. The selection process is shown in Figure 1.

Study quality
Two investigators (T.K. and V.I.-G.) separately assessed the risk of bias of included articles and a third investigator (M.S.) compared the results. The methodological risk of bias of these studies was checked according to the Cochrane Handbook for Systematic Reviews of Interventions,14 which includes the following seven parameters: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. Each parameter is scored as high, low, or unclear risk of bias. Studies were considered to be at high risk of bias if random sequence generation or allocation concealment showed a high or unclear risk.

Data synthesis and statistical analyses
As shown in Figure 1, a total of three articles were identified. Haemoglobin A1c was suitable for meta-analysis. Review Manager Version 5.4 for Windows (The Cochrane Collaboration, Oxford, UK) was used to carry out a meta-analysis to explore the effect of gamification on T2DM tertiary prevention on glycaemic control expressed by HbA1c. The weighted mean difference with 95% confidence interval (CI) as the effect size was calculated for HbA1c and was compared at pre- and post-changes for two comparative groups (with vs. without gamification). Random effects modelling was performed because of the variability of duration, delivery, and assessment across studies. Heterogeneity was assessed by Q statistics with $I^2 > 75\%$ being consistent with a high level of heterogeneity.15 All tests were done at a 5% significance level. For factor-related factors other than HbA1c, Lystrup et al. demonstrated that mean (95% CI) daily step count for the intervention group at the end of the first month was 6919 (6000–7832) and to searching formula, one article19 used both fasting blood glucose and HbA1c as the outcomes. Another article20 set HbA1c and step counts as the outcomes. A total of 704 patients were included in the three RCTs. The study of Kempf and Martin19 was analysed at the time of the primary analysis because two groups were not compared in the secondary analysis. One study was from Europe (Germany19) and two were from the USA.18,20 The rate of male participants and mean ages of participants ranged from 46% to 94% and 60 to 63 years, respectively. The sample size ranged from 120 to 456. Baseline characteristics were not significantly different between the intervention group and the control group. Diagnosis of patients included only T2DM. The details of patient parameters are shown in Table 1.

Types of gamification and characteristics of interventions for type 2 diabetes mellitus
Included studies used devices that provide gamification in the intervention group during the study period. They included a Fitbit Charge20 (Fitbit Inc., San Francisco, CA, USA), the Fitbit® application, and the WhatsApp® application (WhatsApp Inc., Santa Clara, CA, USA),20 a spaced education game used an automated system (Qstream Inc., Burlington, MA, USA),18 a Wii® console, a balance board and the exercise game Wii® Fit Plus (Nintendo of Europe GmbH, Frankfurt a.m., Main, Germany).19 There were various kinds of gamification contents in the studies. Details about the intervention contents are described in Table 2.

Reasons for dropout
The study periods ranged from 3 to 6 months and the mean period was 5 months. The mean completion rate among the included trials was 88.4% (range 80.0–92.1%). Common causes for drop-out included personal reasons,20 medical reasons,20 and technical problems with the device.19 One article18 did not report precise reasons for dropout.

Study quality
The risk of bias was assessed in each study. All four studies demonstrated a low risk of bias for random sequence generation and allocation concealment. Blinding of participants and personnel was not possible due to the nature of the intervention. Blinding of outcome assessment was not demonstrated in all studies. Both attrition and reporting bias were low. Overall, all four studies were thought to be of high quality (Figure 2).

Outcome
Three studies described HbA1c. Figure 3 illustrates the meta-analysis and forest plot results performed for HbA1c between the two groups. There was no significant heterogeneity in the studies and all three studies showed decreased HbA1c in the intervention group compared to the control group in the overall effect [mean difference -0.21%; 95% CI (-0.37 to -0.05); $P = 0.01$; $I^2 = 0\%$]. In terms of searching formula-related factors other than HbA1c, Lystrup et al.20 demonstrated that mean (95% CI) daily step count for the intervention group at the end of the first month was 6919 (6000–7832) and

Results

Study characteristics
Two RCTs met the selected inclusion criteria. One more RCT was extracted from the references18–20 (Table 1). As for factors related

$R^2 = \frac{(SD_{\text{pre}} - \text{mean})^2 + (SD_{\text{post}} - \text{mean})^2}{(SD_{\text{pre}} + SD_{\text{post}})^2}$
Mean daily step count for the control group at the end of the first month was 7668 (6714–8622) and 7069 (6006–8134) at the end of the sixth month. Although step counts decreased significantly over time irrespective of group, the decrease was smaller in the intervention group than the control group.

Discussion

This systematic review demonstrated that the use of gamification shows a positive impact on glycaemic control expressed by HbA1c in T2DM. This observation suggests that using gamification can be a useful addition to the treatment of T2DM patients.
There are different types of gamification in the included articles, which used a smartphone application, an online game, and a home video game console. The dropout rate for the included studies in our review was <20% in all studies, which is appropriate for a good RCT. Gamification has several elements which includes game components, game dynamics, and game mechanics. As for game components, one study prepared a gift for high scorers of gamification. In terms of game mechanics, gamification in three studies provided a leaderboard to patients: Wii Fit Plus is indeed a game. Although each included article has different types of gamification and there is not enough evidence to decide which methods are the best, all interventions have elements of gamification with various approaches. In general, the more an application is focused on education for patients, the less attractive it becomes. Conversely, using these gaming aspects is important for patients because ‘funology’ of gamification, meaning the science of enjoyable technology, may improve their adherence and empowerment.

The meta-analysis demonstrated that HbA1c was significantly reduced in the intervention group compared to the control group without heterogeneity. An earlier meta-analysis investigating the efficacy of pharmacological therapies demonstrated that the amount of HbA1c reduction essentially depends on baseline HbA1c. This was also the case in our meta-analysis: the baseline HbA1c was higher in Kerfoot et al. than in the two studies of Lystrup et al. and Kempf and Martin, explaining the larger decrease in HbA1c in the study of Kerfoot et al. However, the positive result remained the same when performing the analysis with the standardized mean difference method. Moreover, the HbA1c drop in this review is smaller than ‘classical exercise interventions.’ Thus, gamification is an interesting addition on top of such classical exercise programs, but it is not a stand-alone intervention.

As for the mechanism of how gamification impacts glycemic control, the described hypotheses are as follows. Game-based interventions have been shown superior to controls in improving health-related quality of life, muscle strength, and balance. Additionally, it has been reported that high levels of physical activity were associated with a lower HbA1c and that physical activity improves glycemic control and complications of cardiovascular diseases. In a recent pilot study, an application offering diabetes education, an electronic diary, and a virtual coach assured high compliance and weight loss for subjects with prediabetes. The previous articles stated that the use of home-based exercise intervention systems such as the Nintendo Wii Fit resulted in a significant enhancement of balance and had a significant impact on total physical activity. There were no VR studies in the included articles, but Lee and Shin reported that VR with video gaming technology (EyeToy games) has a positive impact on daily activity in old adults with diabetes. Virtual coaching can assist in teaching participants coping strategies for stress management as well as teaching them specific training exercises. As mentioned in this review, one included study showed that gamification factor might influence the maintenance of step count and improved the glycemic control. This mechanism is consistent with the reports described above. Additionally, Kerfoot hypothesized that HbA1c would be impacted via increased medication adherence. In the study of patients with prediabetes, the application with gamification which was intentionally planned to provide various elements to engage the widest range of different curiosity, learning styles, and usable time improved glycemic control.

Although the gamification type may be related to the result, exactly which game type is the best is unclear from the current data and there are no consistent methods for evaluating these features. Gamification often helps to motivate participants to exercise and it could take advantage of group dynamics to motivate patients in terms of the duration of the exercise period. Virtual social interaction with peers or unknown patients created by team-based dynamics is also effective for changing their behaviour. These mechanisms might contribute to the positive results.

Demonstrating durability still remains a problem and a future task. Kerfoot et al. do not report health outcome data beyond 12 months and thus cannot determine the degree to which the improvements in HbA1c are durable. Future research is needed to determine the long-term effect of gamification on health parameters. Recent research focuses on combining activity trackers and gamification. An example is the game Pokémon Go for which health benefits have been reported. As technology nowadays allows games and activity trackers to be easily combined, similar games and possibly health benefits are expected to follow in the coming years. Furthermore, co-creation with patients is necessary for the apps and games to work most effectively. In the light of the ongoing COVID-19 pandemic, gamification offers the advantages of enabling patient care without physical contact and with flexible timing reducing the need for transport to the hospital by the patient. For future implementation of this technology into clinical practice and future guidelines, there are several barriers to be addressed: (i) the need for healthcare providers to be trained and to gain digital literacy; (ii) reimbursement issues; (iii) validation of gamification technology in a healthcare context; (iv) evidence of safety and trustworthiness; (v)
liability of medical professionals who check the data and (vi) security and privacy problems.32

Further research is needed, and performing new RCTs with gamification technology with long-term follow-up could be a first next step. Additionally, gamification with different training subtypes (endurance vs. resistance training; high vs. low volume of exercise) and the impact of patient phenotype on outcomes should be investigated. This systematic review aims to pave the way for possible future RCTs.

#### Limitations

This review has limitations. No attempt was made to include the grey literature. In all trials, there was a significant risk of bias because blinding of participants is not possible due to the nature of the technology. Because of the novelty of the topic of gamification, the number of included studies was limited.

However, if those studies in which the intervention only partially consisted of gamification would have been included, heterogeneity of the intervention would have been unacceptably

| Articles                  | Types of the gamification | Contents of intervention                                                                 | Contents of control                                                                 | Outcome                                                                                      |
|--------------------------|---------------------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Lystrup et al.32         | A black Fitbit Charge®, the Fitbit® application, and the WhatsApp® application | Subjects were assigned to a virtual fitness group with nine other individuals from their randomized block. Every subject was a virtual ‘friend’ with the rest of the group and was able to see a ‘leaderboard’ which tracked individual step counts and ranked them in order. Within their smartphone Fitbit® applications, subjects were able to see in real time their daily step counts in comparison with the rest of their group on a ranking board. | Subjects were not assigned to any virtual support groups. Their step counts were visible only to themselves and the research coordinator. They did not interact with any other members of the study. Subjects were allowed to use the normal functions of their Fitbit® applications but did not allow them to make other virtual friends on the Fitbit® application. | Mean HbA1c in the intervention group dropped from 7.4% to 7.2%, and the control group reduced from 7.1% to 7.0%. However, means between groups overtime were not significantly different ($P=0.364$) |
| Kerfoot et al.18         | A spaced education game used an automated system | Patients were sent single or multiple correct answer questions focused on DM management every week via e-mail or mobile application. Points were earned based on performance on the questions. Patients were assigned to a team based on their geographic region. Individual and team scores were posted on leaderboards. At the end of the game, all members of the two teams with the most points received a gift certificate to an online store. | Same system in the intervention group was used but patients were sent questions of not DM but civics content derived from the US Citizenship and Immigration Services Practice Test. | Patients in the intervention group had significantly greater reductions in mean HbA1c than those in the control group (-2.9% and -2.6%, $P=0.048$) |
| Kempf and Martin19       | A Wii® console, a balance board and the exercise game Wii® Fit Plus | Patients were instructed to perform a balance board and exercise game using a Wii® console for at least 30 min/day during the 12 weeks. | Patients received the routine DM care (quarterly visits to the attending physician, check of HbA1c, etc.) during the 12 weeks (and received the intervention 12 weeks later). | The reduction in HbA1c differed significantly from zero only in the intervention group (-0.3%), but not in the control group (-0.1%). HbA1c values were not significantly different between groups at baseline or after the 12-week study period. |

DM, diabetes mellitus; HbA1c, haemoglobin A1c.
high for further analysis. While the effects of body weight and glucose-lowering medications are considered important, none of the papers reported these as being confounding factors.

### Conclusion

This systematic review and meta-analysis demonstrated that using gamification for diabetes management has a short-term positive effect on glycaemic control expressed by HbA1c in patients with T2DM. Gamification is worthy of further exploration in the ongoing COVID-19 era.

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**Lead author biography**

Toshiki Kaihara joined the Division of Cardiology, Department of Internal Medicine, St. Marianna University School of Medicine, Japan, as an Assistant Professor in 2018. He has worked in a remote island in Japan for 4 years and focused on a home blood pressure telemonitoring system in his PhD thesis. He had been studying in Hasselt University, and the Heart
Centre Hasselt, Jessa Hospital, Belgium, in order to learn digital preventive cardiology since 2020. His areas of expertise include primary/secondary prevention in cardiology using digital technology, telemonitoring system, and gamification.

**Supplementary material**

Supplementary material is available at European Heart Journal Open online.

**Conflict of interest:** none declared.

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**Data availability**

All dataset analysed are included in this manuscript and supplementary materials.

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