

CHANGES IN PATIENT REPORTED OUTCOMES, ATTITUDES AND HEALTH BEHAVIORS IN 606 PEOPLE WITH DIABETES FOLLOWING 2 MONTHS USE OF THE DRUGSTARS HEALTH APP.

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Background

- Suboptimal medication self-management and persistence with required medical therapy are key barriers to achieving the full population health potential of new therapeutic innovations (1).
- The cause of suboptimal active engagement in own disease and poor adherence is multi-factorial, and interventions must consider system, disease, treatment and individual patient factors (1)
- Most patient adherence and support programs struggle to 1) demonstrate impact on patient-important parameters including higher order patient autonomy and self-efficacy constructs and 2) achieve scalable population health impact due to regulatory, commercial, health system and consumer outreach challenges.
- DrugStars is a first-of-its-kind generic patient app innovation aiming to improve patient-important behaviors and outcomes related to medical therapy. Its low-intensive, low-cost adaptable generic intervention amenable for broad consumer outreach is hypothesized to provide a potential for high public health impact.
- The DrugStars app provides users with *positive* reminders for taking medicines and rewards in the form of opportunities to do good by donating earned stars to patient charities.
- The DrugStars app aims to improve motivation and attitudes related to medicine use, adherence related to forgetting, and overall perceived well-being or quality of life related to a therapy.

Study objectives

To explore changes over 2 months in first time users with diabetes of the MVP version of the DrugStars app on:

- Self-reported adherence to medical treatment
 - Motivation to follow medical treatment
 - Active engagement in own treatment
 - Active engagement in doing good
 - Patient important diabetes outcome endpoints (PRO)
2. To examine associations between actual app usage and achieved benefits during the study period.

(This study also included the collection of MEA data for all users and assessment of user value experiences and health motivation preferences reported elsewhere).

Methods (1) Intervention

The first MVP version of the DrugStars App was the intervention in this pilot study. The MVP used did not include the DrugStars personalized feedback feature linked to the user's MEA or key flexibility features developed for diabetes users after the study.

The DrugStars app is free to use and available in Scandinavia, US and UK. Its main features are shown below (see also figure 1):

- Users download the app and sign up by registering their medicines, indicating name, schedule and dosage.
- Users receive positive audible reminders to take their medicine at the scheduled times by default.
- Users earn "stars" for each dose of medicine they are registered to take. Users earn extra stars for completing the 10 question MEA* Index for each medicine. In the study version, no feedback was provided to users based on their responses.
- Users then use their earned stars to donate to a patient charity of their own choice listed in the app. The DrugStars company converts star donations into real money donations to the charity at no cost to the user. Positive feedback is provided back to users about the benefits that their donations help create.

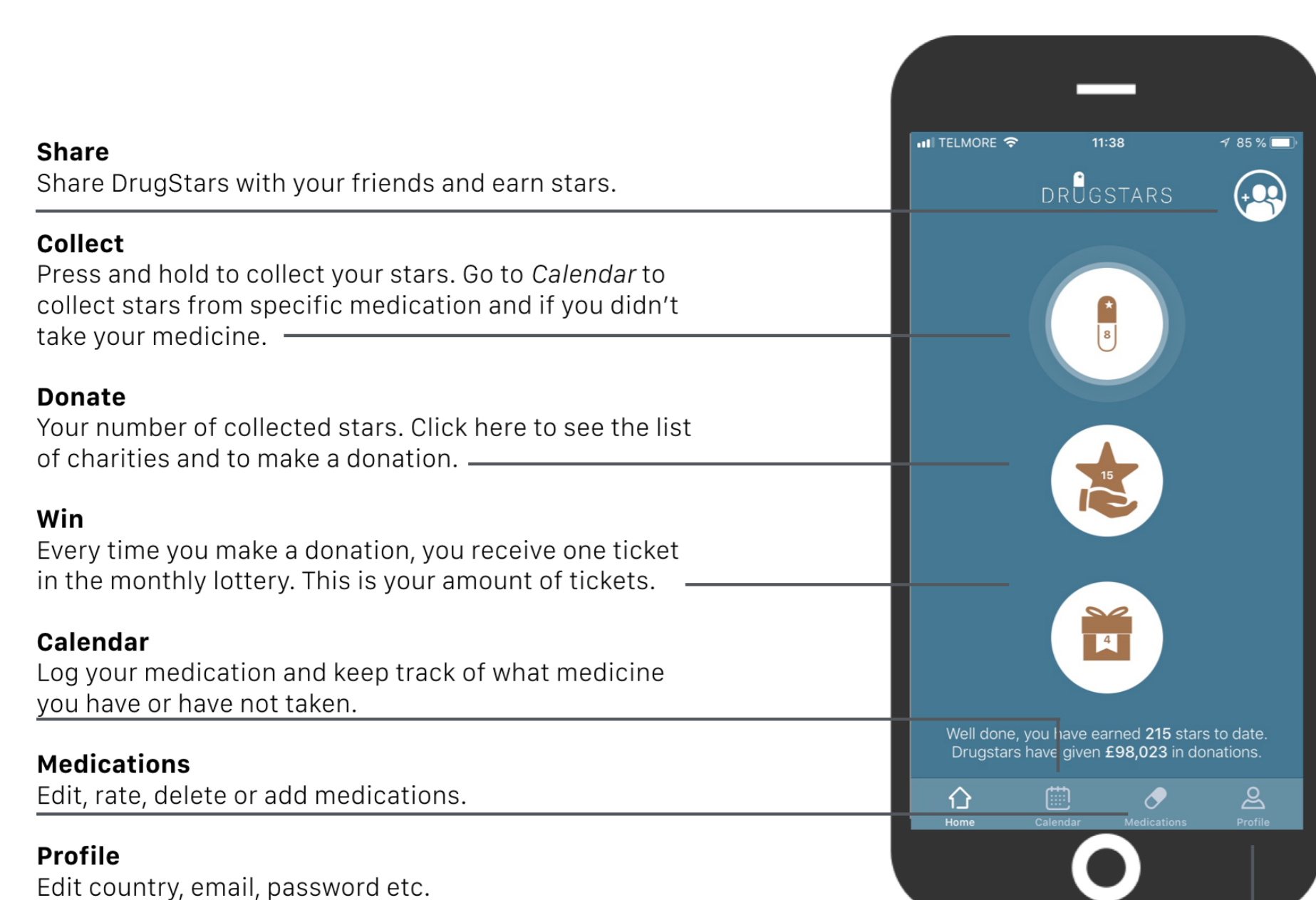


Figure 1. Main features of the DrugStars app for iOS/android (6)

Method (3) Questionnaire design

- Study questionnaires were developed using previously validated and newly developed PRO items mapping on to a theoretical latent construct model. Study design and items were designed involving PWD using PEQC (2).
- Scale reduction and global essence items were used to optimize domain coverage while ensuring high survey patient acceptability. The MEA index was completed by all users for each medicine and validated using classical psychometry.
- Pre-study qualitative patient data were analysed thematically using emergent coding to inform questionnaire development.
- Primary endpoints of adherence, engagement and QOL were confirmed to correlate with clinical indicators for diabetes.

Method (4) Recruitment and study flow

This is a pragmatic real world pre-post pilot study design. Patient recruitment and study flow is depicted in figure 2. Data were collected at baseline, month 1 and 2 using a secure online survey system. In-app usage and questionnaire data were collected on an ongoing basis during the study period.



Figure 2. Overview of study flow.

Results (1) Study participants

1495 were invited, 924 signed consent and completed baseline. 606 completed all assessments (baseline, month 1 and 2 (table 1)). Participants were invited to use the app to the extent they wished. 288 were designated as app users at follow-up and 287 as non-users. ITT as well as subgroup level analyses were conducted.

Variable	Level	Month0	Month1	Month2
Gender	Male	331 (36)	225 (34)	206 (34)
	Female	581 (63)	427 (65)	396 (65)
	Not reported	10 (1)	5 (1)	4 (1)
	12-18 years	0 (0)	0 (0)	0 (0)
Age	19-24 years	10 (1)	5 (1)	3 (0)
	25-34 years	18 (2)	10 (2)	7 (1)
	35-44 years	69 (7)	41 (6)	37 (6)
	45-54 years	147 (16)	98 (15)	87 (14)
	55-64 years	263 (29)	159 (24)	176 (29)
	65-74 years	305 (32)	230 (35)	218 (36)
	74-85 years	99 (11)	78 (12)	73 (12)
	86 years or older	7 (1)	5 (1)	5 (1)
Diabetes type	Not reported	4 (0)	1 (0)	1 (0)
	Type 1 diabetes	246 (27)	147 (22)	128 (21)
	Type 2 diabetes	453 (51)	494 (75)	464 (77)
	Other type diabetes	15 (2)	11 (2)	10 (2)
Do you use an electronic device for reminding you to take your medicine today?	I have not been diagnosed by a doctor	0 (0)	0 (0)	0 (0)
	Not reported	8 (1)	5 (1)	4 (1)
	Yes	79 (9)	53 (8)	48 (8)
	No	836 (91)	600 (91)	554 (91)
Medication type	Not reported	7 (1)	4 (1)	4 (1)
	Tablets	629 (68)	476 (72)	446 (74)
	Insulin	450 (49)	300 (46)	269 (44)
	Other medicine injected	119 (13)	80 (12)	74 (12)
Diabetes duration	I do not get medicine for my diabetes	0 (0)	0 (0)	0 (0)
	Less than 1 year	0 (0)	0 (0)	0 (0)
	More than 1 year	184 (20)	138 (21)	125 (21)
	More than 5 years	241 (26)	176 (27)	164 (27)
	More than 10 years	491 (53)	340 (52)	314 (52)

Table 1. Characteristics of the study population.

Results (2) Improvements at 2 months follow-up.

ITT analysis.	PP2: Month2 - baseline	Cohens D	P-value
Patient adherence			
How often did you not take your medicine as agreed with your doctor or nurse, regardless of reason.	0,06 (n=597)	0,08	0,0412
How often did you forget to take a dose of your diabetes medicine?	0,15 (n=599)	0,22	<0,001
How often did you take your diabetes medicine too late/too early?	0,14 (n=581)	0,16	<0,001
Patient engagement in medical care			
I always try to understand exactly how each of my medicines work. (engagement)	0,21 (598)	0,22	<0,001
I don't always take good care of myself, because I don't like to be reminded that I have diabetes (avoidance)	0,14 (600)	0,12	0,0032
Diabetes related emotional distress			
PAID-1 (worry about risk of serious complications) (3)	0,22 (594)	0,20	<0,001
Perceived changes at month 2 (>3 indicates improvement)			
Motivation to adhere to medical treatment	3,17 (602)	0,36	<0,001
Ability to remember medicine	3,18 (603)	0,33	<0,001
Interest in helping patient charities make a difference	3,16 (601)	0,31	<0,001
Sense of control of my blood sugar	3,13 (602)	0,28	<0,001
Attitude towards my diabetes treatment	3,14 (603)	0,27	<0,001
Mood when taking my medicine*	3,09 (603)	0,21	<0,001
My control of my blood sugar	3,14 (602)	0,24	<0,001
My physical health	3,07 (602)	0,11	0,0069
Need to contact my healthcare providers	3,03 (603)	0,09	0,0264

Table 2. All analyses were adjusted for multiple testing. Controlling for treatment, type, age, gender. All endpoints in study either had either a positive change or no significant change at follow-up. For normally distributed data, one-sided t-test was applied and for non-normally distributed data one sample non-parametric Wilcoxon tests were used. P values were corrected using the method of False Discovery Rate adjusted (FDR) (5) to correct for multiple-testing. (SAS statistics software package). No differences were found between completers and drop-outs which influenced outcomes.

Results (3) Association between app use and benefits

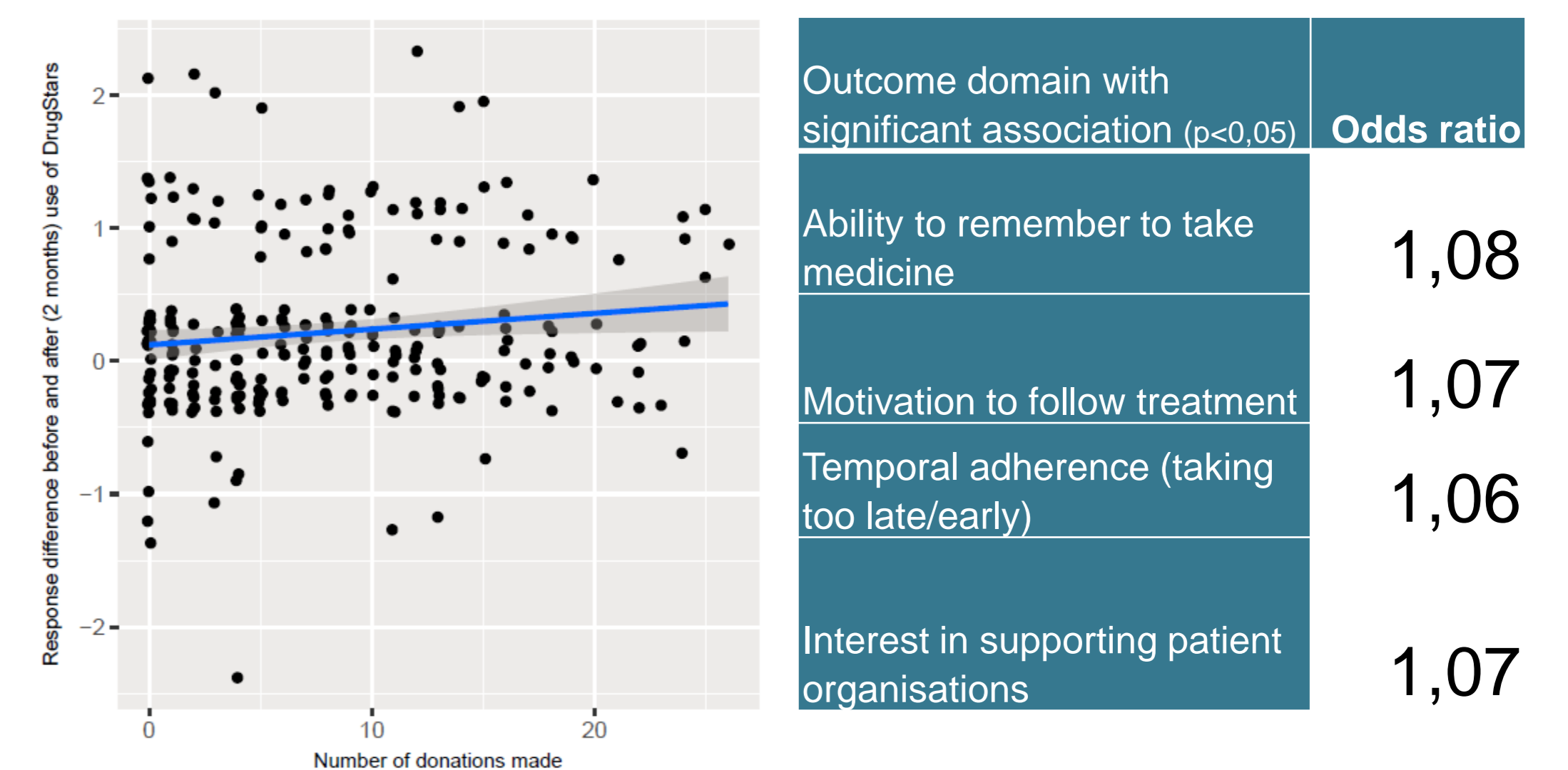


Figure 3. Association of pre-post improvements in remembering medicine doses at 2 months follow-up with number of donations.

Table 3. Odds ratio for reported benefits by donation frequency. Regression analysis. Greater donation activity was associated with slightly greater likelihood of benefit at follow-up.

Results (4) Outcomes for app users vs non-users.

Primary endpoints with statistically significant group differences at month 2	Users of app (n)	Delta	Non-users (n)	Delta	p-value	FDR adj.
Forgetting take medicine (PP2)	301	0,22	298	0,08	0,00404	0,025971
Ability to remember medicine (PC)	304	3,25	299	3,11	0,00006	0,00009
Interest in helping patient charities make a difference (PC)	303	3,24	299	3,07	0,00004	0,00009
Diabetes Quality of Life (DIDP) (PP2) (4)	293	0,19	285	-0,16	0,00156	0,01404

Table 4. Statistical analyses controlled for age, gender, type of diabetes and treatment type.

Results (5) Discussion

- ITT analyses showed significant (very small-modest) improvements on adherence, motivation and patient engagement in own care and in charity donations as well as on diabetes distress (table 2).
- In-app donation activity was selectively associated with an adherence benefit indicative of donations having its own effect (figure 3 and table 3). This was supported by the user value experience assessment showing 95,5% of users had a value experience of the donation feature and 74,5% of the reminders.
- App users showed significantly greater improvements at month 2 compared to non-users on both adherence, active engagement and quality of life (Table 4).

Conclusions

- The DrugStars MVP app resulted in statistically significant improvements (small/modest) in adherence, motivation, active engagement and QOL indicators in 1st time users with diabetes.
- Specific in-app behaviors were significantly associated with user benefits. App users benefited significantly more than non-users.
- Our data suggests that the charity donation feature of the DrugStars app may have unique motivational benefits.
- To our knowledge this is the first study to suggest multiple PRO domain benefits of a generic donation feature for medicine.
- Studies are now warranted to assess the impact of the improved DrugStars app on PROs and MEA scores in a large scale RW set-up to model its full cross-disease public health impact potential.

Limitations

- The pilot study was done using a MVP app version in 2017 which did not have key convenience features considered key to insulin users today. Repeating the study in English speaking countries is proposed.
- Effect sizes ranged from very small to moderate and it was not a randomised controlled study design. Further research is therefore required to further assess clinical relevance and causal relationships.

Abbreviations

MVP: Minimal viable product, ITT: Intention-To-Treat Analysis, PRO: Patient Reported Outcomes, QOL: Quality of Life, FDR: False Discovery Rate (5), MEA: The DrugStars Medicine Experience and Attitude Index, PP2: Pre-Post (Month2-baseline), PC: Perceived Change, PWD: People with Diabetes, PAID-1: Problem Areas in Diabetes.

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