

Effect of an Automated Advice Algorithm (CloudConnect) on Adolescent-Parent Diabetes-Specific Communication and Glycemic Management: A Randomized Trial

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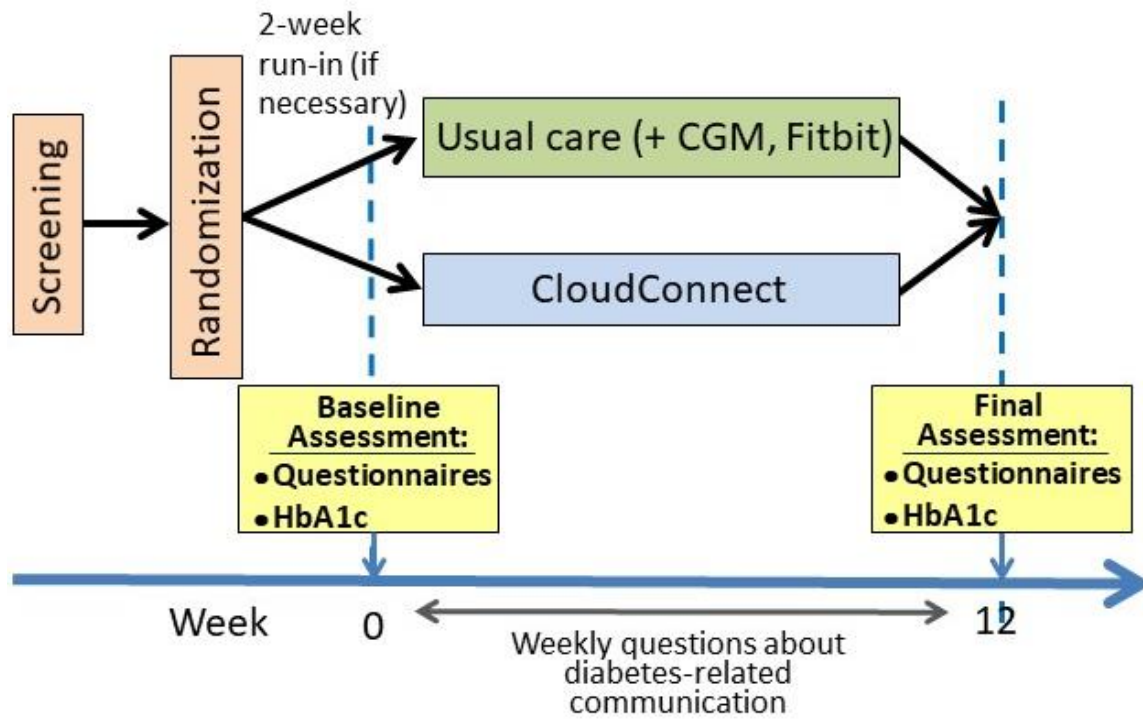
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Supplementary Figure 1: Study Design



Supplementary Figure 2: Weekly Report Example

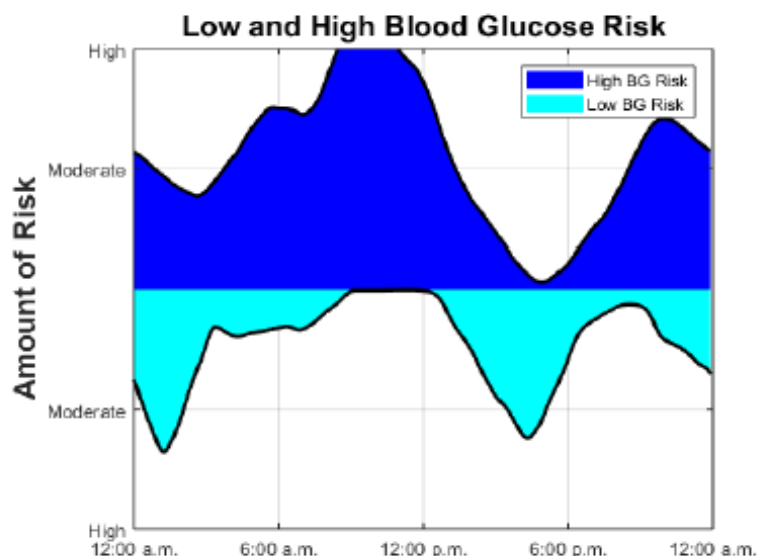
CloudConnect Weekly Report - 56106

Wednesday March 27th - Tuesday April 4th, 2019

BG Statistics. These are based on available blood sugars during the dates listed above.

Average BG (mg/dL)	Events (<70 mg/dL)	Time-in-Range (70-180 mg/dL)	% Time (> 180 mg/dL)
169	14	58%	40%

Low and High BG Risk Graph. This graph shows times where you are at risk for low or high blood sugar. The areas where the blue curves are bigger mean that we saw lots of low or high blood sugars during that time. If there is risk for both at a certain point that means that there have been both low and high blood sugars at that time.



Achievements

- Great job! You increased your time in range by 4% since the last report!
- You wore your CGM for 92% of the days in this report. This information will help us help you!

Suggestions

- We noticed from 7:25 a.m. to 12:55 p.m. that you had a pattern of high blood sugars. It is unclear if you exercised during this time. Please make sure that you are wearing your fitbit at all times. This will let us see where we can help to improve your blood sugar numbers.
- We noticed from 4:25 p.m. to 4:55 p.m. that you had a pattern of low blood sugars. It doesn't look like you exercised during this time. Consider decreasing your insulin dose at the meal prior to this time.

All recommendations are meant to be considered in the context of the care you receive from the medical team at your diabetes clinic.

Supplementary Table 1: Family Communication Inventory

Family Communication Inventory *

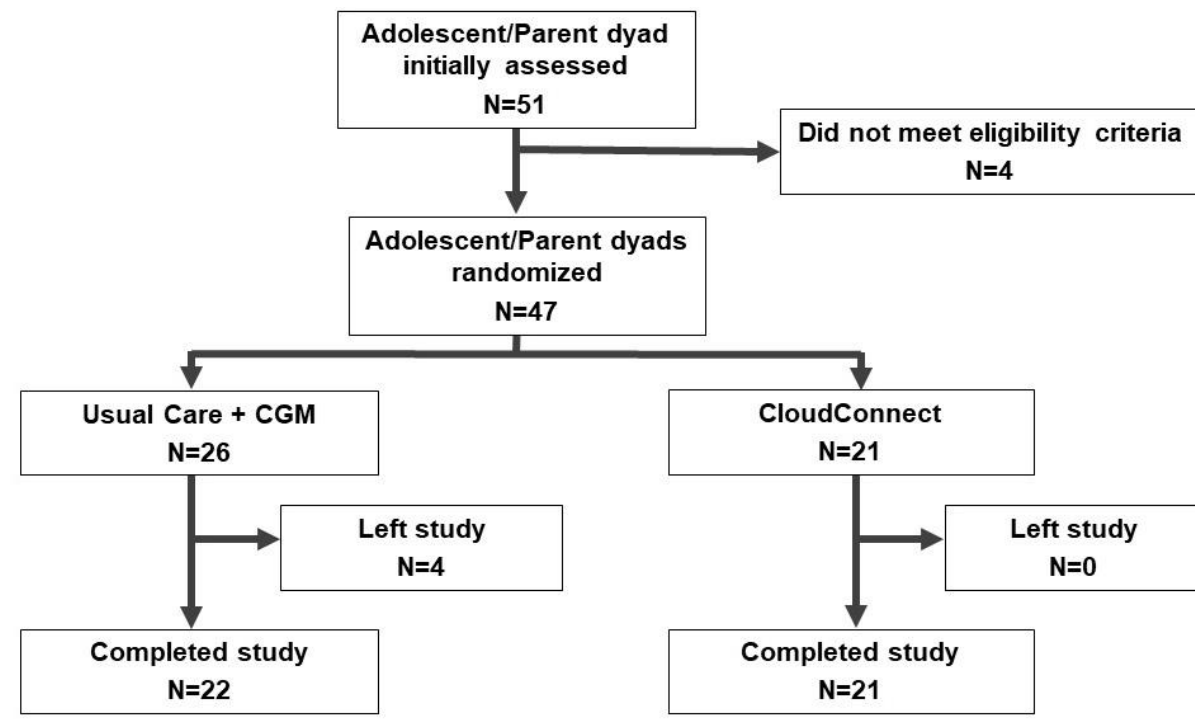
In the **PAST WEEK**, how many times have you and your parent/child done the following and how positive or negative were these interactions overall. Items that are stated to be discussed “Never” will automatically have the tone of communication categorized as NA = not applicable.

1.	Discussed insulin dosing of a particular meal:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very negative	NA
2.	Discussed insulin dosing of an particular high blood sugar:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very negative	NA
3.	Discussed treatment of a particular low blood sugar:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very negative	NA
4.	Discussed missed insulin boluses:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very negative	NA
5.	Discussed overall blood sugar control:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very negative	NA
6.	Discussed frequency/number of low blood sugars:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	egative	Very negative	NA

7	Discussed frequency/number of high blood sugars:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very negative	NA
8.	Discussed adjustment of insulin:carb ratio:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very Negative	NA
9.	Discussed adjustment of Lantus/basal rates:	Never	1-2 times	3-5 times	Daily	Multiple times daily	
	Was this communication positive or negative:	Very positive	Positive	Neutral	Negative	Very Negative	NA
10	Most common forms of communication : (check all that apply):	In person	Phone	Text	Social media (Facebook, Twitter, etc.)	Other (list):	

* For communication frequency questions, scoring of responses ranged from 0 for “never” to 4 for “multiple times daily.” For communication tone questions, scoring of responses ranged from 0 for “very negative” to 4 for “very positive.”

Supplementary Figure 3: Enrolment Flow Chart



Supplementary Table 2: Self-management and shared responsibility between control and CloudConnect.¹

	UsualCare+CGM ¹ N=21		CloudConnect ¹ N=20	
	Adolescent	Parent	Adolescent	Parent
Child self-management baseline	4 (2, 7)	4 (1, 9)	5IQR (3, 9)	6.5 (3, 10.5)
Child self-management final	4 (2, 6)	5.0 (4.6) CI (2.8, 7.2)	4 (3, 9.5)	6.7 (3.5) CI (5.0, 8.3)
<i>P value difference baseline-final</i>	<i>0.790</i>	<i>0.530</i>	<i>0.467</i>	<i>0.776</i>
Child-parental responsibility baseline	23.3 (4.5) CI (21.2, 25.3)	22.5 (4.2) CI (20.6, 24.5)	20.7 (4.8) CI (18.4, 23.0)	20.6 (2.8) CI (19.1, 22.1)
Child-parental responsibility final	23.1 (4.7) CI (21.0, 25.3)	25 (21.0, 26.0)	21.3 (3.1) CI (19.8, 22.8)	21.0 (19.5, 23.0)
<i>P value difference baseline-final</i>	<i>0.851</i>	<i>0.004</i>	<i>0.568</i>	<i>0.217</i>

1. Data shown for normally-distributed variables are mean (SD) and 95% confidence interval (CI), and for non-normally-distributed data median (intraquartile range). Comparisons utilized independent t-tests for variables that were normally-distributed with equal variances and Wilcoxon signed-rank tests otherwise.

Supplementary Table 3: Comparison of quality-of-life as measured by MY-Q and WHO-5 between UsualCare+CGM and CloudConnect.¹

	UsualCare+CGM N=22	CloudConnect N=20	
My-Q baseline	22 (20, 28)	26 (23, 31)	0.339
My-Q final	95.8 (10.7) CI (22.1, 26.7)	93.5 (11.9) CI (23.4, 27.3)	0.510
<i>P value difference baseline-final</i>	0.289	0.701	
WHO-5 baseline	68 (56, 72)	64 (52, 72)	0.638
WHO-5 final	58 (48, 68)	64 (60, 72)	0.210
<i>P value difference baseline-final</i>	0.148	0.952	

1. Data shown for normally-distributed variables are mean (SD) and 95% CI, and for non-normally-distributed data median (intraquartile range). Comparisons utilized independent t-tests for variables that were normally-distributed with equal variances and Wilcoxon signed-rank tests otherwise.

Results of Qualitative Questionnaire on CloudConnect Design and Use at Study Completion

Comments addressing how easy the weekly reports were to understand

“On a scale of 1-7, with 1 being very difficult and 7 being very easy, how easy was it to understand the information provided in the weekly reports?”

Adolescent

Mean 5.7 (SD 1.4)
Median 6 (5, 7), n=20

Parent

Mean 6.5 (SD 0.67)
Median 7 (6, 7), n=23

“Can you tell me why you gave the score you did?”

Adolescent, overall positive (n=14 out of 19 comments)

- "Because it's easy to read."
- "They were fairly easy to understand"
- "The graph was mostly easy to understand and the comments made sense."
- "The weekly reports were written very clearly and were easy to understand"
- "My mom explained them so it was easy to understand."
- "I am graphically literate due to science class in school"
- "Because it was simple to read"
- "because it told me my overall blood sugar and how to keep it level and it was very straight forward."
- "My mom told me what they said"
- "Because it seemed easy"
- "it just made sense to me"
- "The bullet points were easy to understand and it was plain and simple."
- "It was easy"
- "The graph and wording was very easy to understand"

Adolescent, overall negative (n=5 out of 19 comments)

- "The only thing I had trouble with was telling how high or low I was to the goal."
- "some of the questions were how often did you argue and my mom doesn't really argue with me about diabetes."
- "Hard to tell the difference between high and normal"
- "I felt as if the graph could have demonstrated likely probabilities (percentages) to make it easier to read"
- "My mom would explain most of it to me"

Parent overall positive (n=21 out of 23)

"Very easy to understand the data and recommendations. The graph was a difficult representation to see on paper but was helpful in waking us up to where our daughter's diabetes management need improvement."

"Visually, it was very easy to read. The charts and graphs highlighted the important information and made it easy to see changes week to week. The bulleted suggestions and achievements were direct and to the point."

"There was nothing hard to understand on the reports. It was all very straight forward."

"Everything was pretty simple."

"There wasn't too much to reading the reports. Very simple and general information."

"It was easy to read the results of the report."

"The information was presented in a very clear graph with a written description."

"The weekly report always gave us two suggestions about changing Anna's insulin. We changed it by 10 percent at a time , either the basal rate or the carb ratio. I think that the reports helped to improve Anna's blood sugar levels . We would love to keep getting the Cloud Connect reports! Thank you!"

"I understood the reports"

"The information was pretty straight forward and easy to read."

"The information provided was useful and clear"

"I feel everything was very easy to understand"

"I liked the achievements and suggestions. We always worked on them and it gave us an open line of communication"

"It was relatively easy."

"I liked the reports better than my clarity reports - they were straight forward and compared my child's activity levels with her glucose levels. I also thought they were extremely positive in wording with "keep up the good work" instead of "get off your butt and exercise""

"I feel the information is pretty straight-forward."

"Appreciated elements that were included in report. Table that showed Average BG, Events, Time-in-Range and % Time was helpful. Bolded headings made it easy to locate information. In terms of design/aesthetics, date information could have been made a little more prominent, was hard to see in comparison to such a large Study heading."

"They were simple to read."

"The weekly report charts were simple to read based on the graph given."

"I printed out the reports and went over them with my daughter. I liked the graph and the helpful hints at the bottom"

"I like that it gave achievements so she always had something positive so there wasn't this attack- so then the suggestion was just that, hey let's look at this. It made for pleasant conversation"

Parent overall negative (n=2 out of 23)

"I found the graph difficult to interpret. "

"Reports were fine but it's hard to identify what needs to be changed when he takes his insulin after eating and stays high"

Comments addressing how useful the weekly reports were in helping to communicate about diabetes

"On a scale of 1-7, with 1 being not at all useful and 7 being very useful, how useful were the weekly reports in helping you communicate with your parents/child about managing your/your child's diabetes?"

Adolescent

Mean 5.4 (SD 1.7)
Median 5 (4, 7), n=20

Parent

Mean 5.5 (SD 1.8)
Median 5.5 (4, 7), n=23

"Can you tell me why you gave the score you did?"

Adolescent, overall positive (n=12 out of 19)

"When I saw them I wanted to be closer to the middle of the chart so I would try harder."

"My parents still yelled at me a lot and we did talk a little bit more about it without them yelling"

"Provided feedback on weekly highs and lows"

"They helped me to see the overall trends in my blood sugar better and I took the suggestions and applied them."

"It made it easy to figure out with my parent what needed to be changed"

"My mom and I would ask each other if we had completed the surveys, and after we both looked at the graph on Thursdays, we would make changes to my insulin together"

"My mom talks to me a lot about my diabetes so it didn't feel very different using the report but the graph was cool to see"

"I could determine when to take more insulin or take it earlier"

"It showed that I wasn't lacking when it came to my diabetes"

"Because we can both understand it"

"because it was very easy to communicate with my parent about what i should do to keep my blood sugar level."

"we just talked about it alot"

Adolescent, overall negative (n=7 out of 19)

"We didn't talk about it much."

"Nothing really. It didn't change anything in terms of communication"

"I didn't really read them too much so my mom just told me what was suggested."

"answering a survey just made me think about my week diabetes wise but not talk more"

"Sometimes we didn't have time to look at the reports so it was difficult to talk with them about that portion of the study."

"They were a bit hard to understand simply because I was not used to them"

"My mom would change my insulin amounts"

Parent, overall positive (n=12 out of 21 comments)

"It was much easier to have a discussion when all the data was right there in front of us."

"It provided an objective, consistent opportunity to look at "data" and trends rather than coming across as a personal attack or criticism."

"It made it easier to understand some times he had the most trouble."

"It was nice to see where her numbers were and be able to show her the results and be able to show her why she needs to be in better in control."

"The reports pointed us out where we needed to change something."

"very helpful"

"There was a lot more information than a standard tester"

"It did open up lines of communication. We were able to talk about his numbers more. "

"I liked the achievements and suggestions. It was a positive experience. It really opened up our communication"

"Everything was self explanatory"

"it was a "reason" to take the time to "sit down" and discuss the managing of her diabetes. The report showed in an easy way to discuss what time of day she was high."

"Showing how his bloodsugars were over the 2 weeks from the report helped us know how to somewhat adjust insulin needs."

Parent, overall negative (n=9 out of 21 comments)

"The reports rarely told us anything we did not already know. We keep a pretty open line of communication already. However, I can see how they may help parents who do not have the time to pay as close attention as we do. I also found that the reports conclusions on when he was exercising and eating were not correct."

"Again the reports were just very general. "

"The information in the reports was often vague. The suggestions were not very specific and often were unable to take into account all factors. It was nice to have the suggestions for my daughter to see and not have to hear it from me."

"I wish it would have given recommendations about to what we should have switched dosing to. I upload pump results so you can see what her numbers are so a recommendation on what to change it to would have been helpful"

"Reports were fine, he does not want to discuss diabetes management at all"

"The section that gave the overview for the week allowed me to encourage my child and to make decisions collectively on changing parameters to her treatment"

"I found the information helpful... the issue is that my son has not been very open about communicating and rarely if ever enters info into his Pdm (like snacks that he doesn't Bolus for). With everything being virtual his sleep, school and activity schedule is not as structured as we're used to either."

"Reports were very helpful, we just didn't always have the time to get together and review them in great detail"

"The information wasn't comprehensive enough to see patterns so we could make necessary changes."

Comments addressing how to make the weekly reports more useful

"What could have made the weekly reports more useful to you?"

Adolescent

"Nothing" or "I don't know" x 10

"If they showed when you bolused and how much."

"If they have a general suggestion on how much to increase or decrease basal rates."

"Suggest insulin parameters based on current patterns to address problems in blood sugar control"

"It didn't tell me anything that I didn't already know"

"If they came to me via text. I don't really check my email so Mom just told me."

"Again, using multiple graphs."

Parent

"Nothing" or "I don't know" x 10

"Cant really think of any..maybe including info on standard deviation"

"More information. You guys have the AP algorithm, all his dosing, CGM and activity data. I know there was way more data you could have dug into to provide useful information to us on dosing. I was hoping for more."

"The information didn't seem all that different than other reports save telling of his steps in the week."

"I wish the reports would often give specific parameters to set the basal or bolus rates at."

"More changes. More emphasis in staying in range."

"Not a thing! He just needs to be open to taking the guidance."

"If my daughter was not a teenage girl with not much interest in her care, it sure would be more useful if she put in more effort to read thru it herself (;"

"Charts that look more like Tandem reports. It would be helpful to see daily/weekly blood sugar charts. And also a chart that shows blood sugar through the whole study would give us an idea of where we started and where we ended the study in terms of getting better blood sugar numbers."

"It would have been helpful to have his doctor chime in or the research doctor tell us how much to adjust the insulin."

Additional final comments

“Is there anything else you would like to tell us about your experience with the weekly reports?”

Adolescent overall positive (n=2 of 4 comments)

“It overall helped out with managing my numbers.”

“It helped a lot with my blood sugar levels”

Adolescent overall negative (n=2 of 4 comments)

“It was espionage hard to follow the reports because it was summer and most weeks were inconsistent with different activities and sports if it had been in the school year with a more consistent schedule than it probably would have helped a lot more”

“The alarm is very loud”

Parent overall positive (n=12 of 16 comments)

“Great tool!”

“I think the Achievements heading was especially important. Kids who are already having to deal with the challenges of their health situation need to have positive messages about their efforts, and this was a really nice way to do that.”

“I liked seeing the % of time within range. That was helpful.”

“They were helpful in engaging my son in his own care and increasing his awareness of how often he was in range, etc. He was more responsive to highs during this study than he typically was previously.”

“They were easy enough. The question phrased about “have you argued” - its a weird term. We discuss things all the the time, we rarely argue about them. ”

“It was great to have a weekly reminder and report to show her the progress or downfalls of her diabetes management.”

“It was nice to see my daughter want to do better after seeing the reports. She often would want to have a lower average than the week before”

“We loved it ,and please let us know when it will be available for the public!”

“They were simple and easy to read”

“These reports just opened up our conversations in a nice way and we only really talked about diabetes on Friday unless there was a low or just something we needed to talk about but the majority of the conversation was when we got the report so she didn’t feel like we were talking diabetes all the time.”

“The fact that my child and I both got the reports emailed to us reminded me to discuss the progress with my child and make changes more often than seeing a pattern weeks later when I would remember to run a clarity report.”

“I found this experience helpful as a Mom of a T1D and feel that if there was a virtual check-in for him to discuss/get suggestions rather than read a report from someone (other than his Mom) it would be helpful at this stage.”

Parent overall negative (n=4 of 16 comments)

"Would have liked specific details and recommendations. During the summer every week was different so possibly having reports on generated on the weekend would be more reflective of a week. For example vacation was one week and squash camp another."

"I feel like it didn't provide us with enough changes. It kept saying he had a good week even if he was in range between 40 - 70 percent of the time. To me, that isn't good control. We had too many swings. Not enough days where we stayed in range all day. Still think he needed alot more adjusting than was suggested."

"Sometimes the suggestions were the same things we corrected"

"Not sure if there is a way to make a version that is more "kid" friendly or a bit more fun BUT I guess it is pretty much kid-friendly as is."