Radcliffe ACC 2022 Late-breaker Discussion: The SuperWIN Trial

Dr Van Spall: I'm Harriette Van Spall, Associate Professor of Medicine, Cardiologist and Researcher from Canada. And I'm delighted to have with me, Dr Dylan Steen, Director of Clinical Trials and Population Health Research, at the UC Heart, Lung and Vascular Institute, University of Cincinnati College of Medicine.
We are here at ACC 2022 to discuss his SuperWIN trial, welcome Dylan.

Dr Steen: Thank you so much for having me. It's great to be able to chat about this.

Dr Van Spall: Yes, I'm excited about this nutrition trial. Tell us about your research question and why you sought about trying to answer it. Tell us the context.

Dr Steen: Sure. So just, first just to credit sort of everyone who was involved with this, this really took an army to be accomplished. And that's my co-principal investigator, Dr Sarah Couch, a team of very diverse interdisciplinary academic co-investigators, and then also leadership from the Kroger Company, the largest supermarket chain in the United States, to really pull this all together and allow SuperWIN to happen.
So, I'll frame this in a bigger way just to get started. For decades, I think we've all realised that the clinical research or the biomedical innovation engine has largely been due to collaboration between academic independent researchers and industries like the pharmaceutical, biotechnology, medical device industries.
And when we go to conferences like ACC, we certainly expect lots of researchers to be presenting data on new compounds, devices, et cetera, sponsored by these industries. What is remarkable is that for different fields, let's say like, dietary education or medication, non-adherence challenges or other issues that we sort of really struggle with on a public health level is, we haven't yet been able to form those types of collaborations with other industries who are perfectly poised to deliver those types of interventions.
So, you can imagine if you are thinking about dietary education, what industry might you think about? Well retail, supermarkets being a type of a retailer in that industry, because those are the places where people make the vast majority of their food related decisions. And it turns out that this industry is located within communities throughout the globe, touching and connecting with their consumers multiple times a week, and of course with the full food inventory of products.
So, for SuperWIN, which was the first collaboration with this company called the Kroger Company, we decided to test a few questions which really have never been tested using rigorous randomised control trials before, because these collaborations had not existed and the first question was, what if you could offer dietary education right in someone's preferred supermarket location without having them to go to some traditional medical facility? What if it could be guided by in-store based dieticians who know the food inventory and also have expertise in nutrition? What if it could be delivered right in the aisles of the store, would that improve adherence to evidence-based dietary behaviour patterns? And what if we could do it via and guide these sections, almost personalise it in a way by using your own purchasing data, to help the dietician and to help you understand how you could do better.
The second question we wanted to understand was, what is the role or actually what is the potential efficacy of all these online shopping tools and other sort of smart and healthcare applications in supporting better dietary intake, better adherence evidence based guidelines? And so, we actually tested whether if we teach you to shop or these dieticians teach you to shop in the physical store environment, versus the physical store environment, plus being trained on online shopping, home delivery, other types of applications to eat better, whether

this sort of combination approach utilising the store's physical environment, as well as its online environment might be even better.
And so, we tested two hypotheses formally, we tested them in a hierarchal testing pattern so that it could troll our alpha error. So, the first test was the former question I mentioned, and the second test was the second. And we did this all on top of a sort of an enhanced standard of care, which is known as a medical nutrition therapy visit.
We enhanced it with additional data which we believe could be available out there in the world, but in this trial, we actually enhanced it so this is on top of enhanced standard of care.

Dr Van Spall: Right. And the participants were identified through primary care clinical networks based on their risk factor profiles, is that right?

Dr Steen: Correct. One, in approaching research with retail based healthcare, we wanted to demonstrate the ability to create integrated care. Nobody wants more fragmentation or care with different provider sets, and different places and less communication.
We believe that you can create integrated care programmes. So, we actually enrolled patients out of our UCHealth Primary Care network, these are primary care physicians, who oftentimes struggle with improving dietary quality in their patients. And those patients were approached, we used our electronic health record system to reach out to them. And patient characteristics that we were looking for was, one, care buyer primary care physician, and then one of three risk factors, either obesity, hypertension, or dyslipidaemia. And then each participant also had to be a shopper in one of our study stores.
We had stores in two states, Ohio and Kentucky. They had to be a Kroger shopper, and they had to be either the primary food planner or shopper for their family. Because we wanted to make sure that they were really sort of, you know, utilising this sort of store environment, and then the education that we delivered to them would be most beneficial to them and their families.

Dr Van Spall: Okay. So, from an operational perspective were the dieticians present in the supermarket all hours of the day, or did the visits have to be coordinated with the dietary counsellor or advisor?

Dr Steen: Sure. So for the purpose of this trial, first thing is all study visits were done in the preferred supermarket location, actually within the retail-based clinic called the Little Clinic. And the times were really chosen based off what was convenient for the participants. Obviously, many of our participants were working full-time, the majority were, so we tried to give them appointments morning, evening, or whatever day of the week would work best for them. But they were scheduled in advance, just so enough time could be carved out to do all the sort of study related procedures, biometric measurements, interviews, et cetera.

Dr Van Spall: And what was your primary outcome?

Dr Steen: So, the primary outcome was change in DASH score. So DASH, as we all know, is an evidence based dietary eating programme, it's very high in fruits and vegetables, whole grains, low fat dairy and so forth. And the challenge in the public has been to take DASH, which we know works and actually translate to the public where dietary adherence is very very low.
So, our primary outcome measured adherence to the DASH diet, and this was measured on a DASH score. In the literature, DASH scores have been designed in many many ways, we

wanted to do something that was really we thought good adhering, understanding adherence of the DASH diet. So, ours was a 0-to-90-point DASH score, 90 being the best possible measure of DASH adherence or perfect DASH adherence, the different components of the score were all the different subgroups and components of the DASH diet. So, we would basically give points for having eaten or not eaten different components that DASH recommends. And so, we looked at change from baseline before someone started their dietary education within SuperWIN to three months, that was our primary endpoint.
And the first test was whether we could increase DASH from standard of care compared to getting interventions within the store, and then the second test was, whether the combination online in-store arm would be increased DASH score greater than the in-store only arm.

Dr Van Spall: Sure. And what were your findings?

Dr Steen: Well, so the first finding, and I'll just give some context, was COVID-19 pandemic hit the trial just like it hit other trials, and in ours, it hit us right in the middle. And so for us, we were doing in-store study visits. We actually had to suspend the trial for a number of months, because the safety of in-person visits was questionable at that standpoint. This was when COVID first came about, but then we did resume afterwards.
So, our findings in our sample size at the end was 247 participants in the overall cohort. And it turns out that in-store supermarket driven purchasing data guided interventions did increase DASH score by 4.7 points compared to an enhanced standard of care arm. And because we hit on that endpoint, we were allowed to test our second endpoint that I mentioned before. And it turns out that adding online enhancements, teaching participants to shop online, to get home delivery, to use these smart and healthcare applications, actually improve DASH score even further above just teaching them within the aisles of the store. So we hit on both in this case, both were statistically significant.

Dr Van Spall: Okay. And what is the relevance of a change in DASH score by the thresholds that you described, just over four-point change? Is there a clinical sort of correlate that this surrogate endpoint signifies?

Dr Steen: So, in our trial we did have secondary endpoints as well. And in this trial we're just small and not designed to look at these secondary endpoints specifically, we did not change blood pressure BMI, or non-HDL cholesterol or triglycerides. But again, we weren't really designed to test those formally, and again, the sample size was only 247 participants.
Now we know from prior studies, both trials as well as observational studies, that improvements in dietary intake, even small, especially if extended over time can have very meaningful and profound hard outcome benefits for our participants.
So, we think these are meaningful. And I think, the sort of the really important thing here is it really gives us a direction which to go. The idea that we can use these stores which are part of the fabric of almost any community out there as a place to deliver dietary education, as well as these new tools, and these changes in shopping behaviour could be beneficial to us.
And I think with the way science sort of works is as we all know, is science is rarely about one particular study. It's about a process of validation for multiple advantage points with multiple different scientific teams.
I think we can continue to enhance the benefits of these interventions, as well as their effects on even secondary outcomes.

Dr Van Spall: Sure. And would you tell us how the DASH score was measured?

Dr Steen: So the DASH score was measured, we used dietary intake recalls. So, our Cincinnati Children's Hospital and Medical Centre, who was one of our partnering systems in conducting this trial, conducted three 24-hour dietary intake recalls at each time point. Baseline three months and six months. And that was the raw dietary intake data that allowed us to then calculate component scores, which led to an overall DASH score at each time point for each participant. And this is a quite a rigorous way of actually assessing dietary intake and assessing adherence to any particular dietary intake pattern.
In a pre-specified analysis, pre-COVID measures of sort of visit attendance, data collection versus, you know, during the pandemic, and the visit attendance prior to the pandemic was around I believe 99% for each specific visit. Which is remarkable in a free-living community based cohort compared to prior studies. So, I think this adds to what you just said about if you can actually deliver education and bring it to communities, bring it to participants, where they are currently shopping, where they are and not disrupting their sort of their lives, that's very very important.
We found the same thing, near perfect diet data collection prior to the pandemic as well. Just sort of showing the feasibility of running these studies when you have such a collaboration. Now during the pandemic, these numbers and don't quote me on the specifics right now I don't have the data in front of me, dropped around 80%. Which is still pretty good prior to, in comparison to previously published studies in this space, but just wanted to sort of highlight that. And I think there is something there where if we can really sort of get at where people live, we can do a better job in delivering something that they, is actually much more palatable to them, which is what we need to do.

Dr Van Spall: So to summarise, in this small clinical trial that was interrupted by the COVID pandemic, you demonstrated that standard of care plus individualised point of purchase nutritional counselling compared to standard of care alone, improved DASH diet scores by what you consider a relevant amount. Although, it did not reduce lipid levels or improve blood pressure management. It nicely demonstrates how a pragmatic intervention in a location that patients use in their day to day lives, can augment clinical care and help support the kind of behavioural and lifestyle interventions that we counsel patients on in our clinical environments.
Thank you so much for joining us this morning, we look forward to your presentation at ACC, and wish you a warm congratulations for this late breaking clinical trial.

Dr Steen: Thank you so much. I look forward to seeing you at ACC.