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HUNTINGTON'S

NEWSLETTER

PAGE 03

**UNPACKING WAVE'S
PRECISION-HD2
HUNTINGTIN-LOWERING
TRIAL ANNOUNCEMENT**

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FUTURE NEWSLETTERS

To continue to receive future issues of this newsletter, we require you to contact us by:

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Know someone else who would like to receive future issues?
We invite them to also contact us!

The next issue will be out mid August 2020. In the meantime we encourage feedback from readers on what you would like to see in the newsletter as well as your submissions for consideration by the editors to be included in future issues. Feel free to include photos. Please have these in by 18th December, 2018 to admin@hdauckland.com

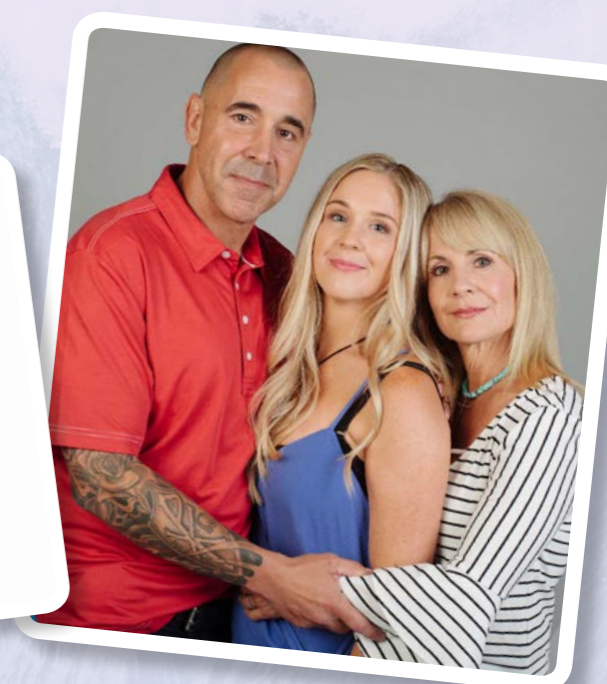


Hasn't it been a fabulously hot summer?!

UNPACKING WAVE'S PRECISION-HD2 HUNTINGTIN-LOWERING TRIAL ANNOUNCEMENT

WAVE LIFE SCIENCES ANNOUNCES THAT ITS ANTISENSE DRUG WVE-120102 HAS LOWERED MUTANT HUNTINGTIN PROTEIN IN CEREBROSPINAL FLUID, BUT INVESTORS SEEM DISAPPOINTED. RATHER CONFUSING – WHAT DO WE KNOW FOR SURE?

BY DR JEFF CARROLL,
JANUARY 03, 2020,
EDITED BY DR ED WILD



DNA-based drugs called antisense oligonucleotides, or ASOs, are now in multiple clinical trials in Huntington's disease, aiming to lower production of the harmful mutant huntingtin protein in the brain. Wave Life Sciences has been running parallel trials of two new ASO drugs, administered by injection into the spine. Just before the new year, Wave announced that the drug in the PRECISION-HD2 trial had successfully lowered the concentration of mutant huntingtin in the spinal fluid. The reduction was quite modest, at 12%, so the company will be adding a higher-dose cohort to both its trials. While the investment community seems disappointed that another trial arm is needed, and we need to see the results in full, to us it's good news that there are now multiple huntingtin-lowering drugs in the world.

LOWERING HUNTINGTIN

The genetic mutation that causes Huntington's disease does damage to the brain by telling cells to make a harmful protein, mutant huntingtin. Reducing production of this protein - or **Huntingtin Lowering** - is the biggest focus of drug development in HD.

A drug called HTTRx made a big splash a couple of years ago when it was reported that it had successfully lowered the production of mutant huntingtin in the spinal fluid of HD patients. That drug has been renamed RG6042 and is now being tested by Roche/Genentech in the GENERATION-HD1 trial which will hopefully tell us whether lowering huntingtin production slows the progression of the disease.

RG6042 is a drug made from DNA that interrupts the protein production chain. DNA drugs like that are called antisense oligonucleotides or **ASOs**.

Wave Life Sciences was the second company to start testing ASO drugs for Huntington's disease. Wave wants to achieve the same aim – lowering mutant huntingtin – but with a twist.

Every person has two copies of the huntingtin gene - one inherited from mom, and one from dad. One abnormal copy is enough to cause HD by causing cells to make the mutant protein. But those cells also produce the normal or healthy version of the protein. Scientists call this healthy version of a gene or protein “wild-type” because it's the one most commonly seen “in the wild”.

Roche's RG6042 has equal effects on the mutant and healthy version of huntingtin - it cannot distinguish between the two production lines and is expected to lower mutant and wild-type huntingtin equally.

Wave's ASO drugs aim to target just the mutant version of the huntingtin protein, leaving wild-type production relatively unaltered.

This is much harder to do, which is why Wave had to design two different drugs, each targeting a little single-letter genetic spelling differences that are sometimes passed down along with the mutation that causes HD. These spelling differences don't do anything in themselves, but they can be used to steer the drug to the mutant side of the protein production line, in people who have the right genetic markers in the right place. Wave estimates that about two-thirds of the HD population will have one or other of the necessary genetic markers to make them suitable for treatment with one of their two drugs.

Wave's two trials launched in 2017. They were called PRECISION-HD1 and PRECISION-HD2, testing drugs called WVE-120101 and WVE-120102 respectively. Within each trial, patients were allocated randomly to treatment with the drug or placebo (injection without any drug). Four different

doses of the drug were tried as the trial proceeded, which is important to remember as we look at the results of this study. The trials were short - about five months' treatment per patient.

HEADLINES

Wave's latest press release sets out the first results from the PRECISION-HD2 trial. The release announces that WVE-120102 **successfully lowered mutant huntingtin** in the spinal fluid, when all of the active treatment arms were looked at together and compared against the placebo-treated group. Wave's announcement gives a figure of about **12%** for the degree of mutant huntingtin lowering.

If a drug is working, we expect higher doses to produce a bigger effect. This is called a **dose-dependent** response, and if you can show it in a clinical trial, it strengthens the case that your drug is doing what you intended. Without giving much detail, Wave's announcement states that the huntingtin-lowering did show a dose-dependent response at the highest doses tested when looking across all of the treatment groups together.

To be clear - Wave has not yet released enough information for us to understand exactly how the amount of mutant Huntingtin in the spinal fluid is related to the dose of the drug given in the PRECISION-HD2 study. We expect that, as commonly happens with these small early trials, more data will become available soon and we'll be able to evaluate this relationship.

Important but easily glossed-over is the primary reason behind the trial: safety. From the information given, the short-term safety looks good. 'Adverse events' were no more common in drug-treated patients than in those receiving the placebo. In itself, that is a very solid result from this first-in-human trial.

APPLES AND ORANGES?

The first person to climb a mountain has a tough job, but gets lots of cheers. The second person to the summit may have an easier time, thanks to the first person mapping out a route - but is likely to be

asked questions like “how did your time compare?” when they get there.

It's similar with drugs. Roche's RG6042 was the first ASO drug to lower huntingtin, and two years down the line, we have much more detail about how they did it and the full results of the trial have been published. It's inevitable that Wave's results will be scrutinised to see how they compare. Such comparisons may not be terribly helpful, because of the important differences between Wave's drugs and Roche's - but let's do it anyway and see what we can learn.

How does Wave's 12% reduction in mutant huntingtin compare? Well, RG6042 reduced mutant huntingtin by roughly 40 to 60% in patients on higher doses. 12% is less than 40%, so that means the Wave drug is less good, right? Not so fast...

Fundamentally, no drug has yet been shown to slow progression of HD, so **we don't know how much mutant huntingtin reduction is ideal**. Furthermore, we don't yet know whether reducing only mutant Huntingtin, as Wave is trying to do, is going to be more beneficial and safer than RG6042, which targets both forms of Huntingtin. That's why we do these studies - so we can figure out what approach is safest and has the biggest impact on HD symptoms.

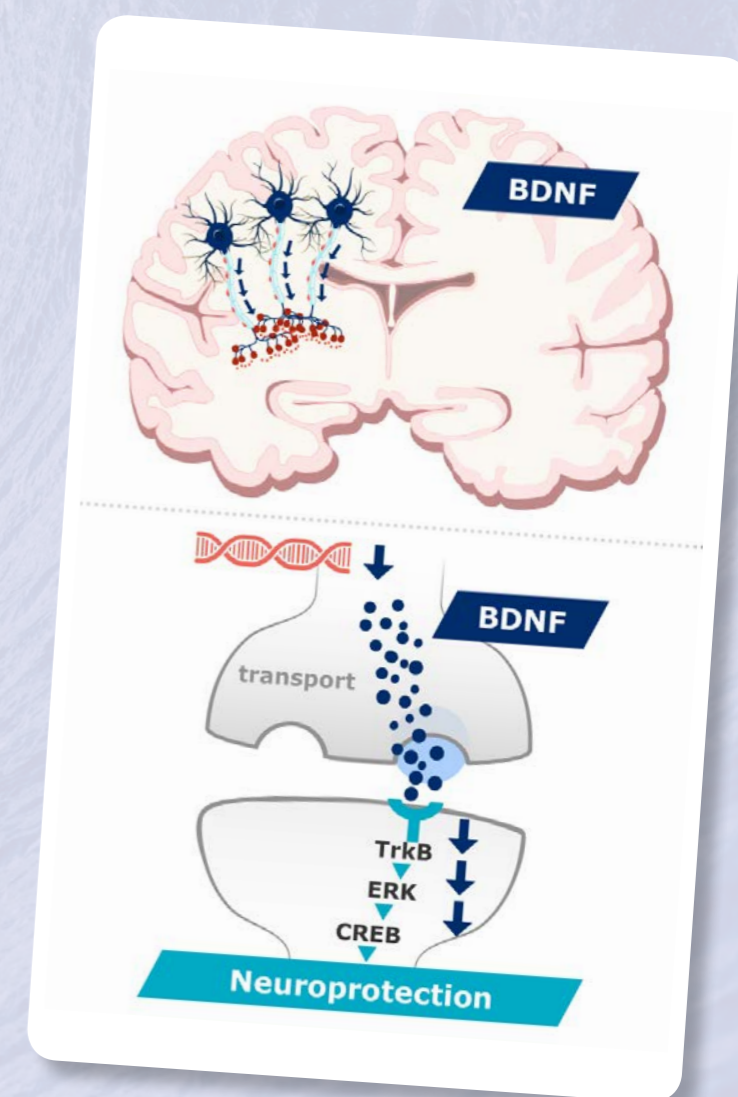
Another important wrinkle to keep in mind is that the doses of drug used in the two trials were very different - the highest dose in the RG6042 study was 120 milligrams and the highest dose tested in the PRECISION-HD2 study was 16 milligrams - that's a big difference!

Based on these results showing their drug was safe at lower doses, Wave has already announced it will now add an extra dosing arm to the PRECISION-HD2 trial, to test higher doses - 32 milligrams per injection. That's twice the amount tested at the highest dose in this trial. So the 12% mutant huntingtin reduction they're reporting may well be a stepping stone to a bigger reduction from a higher dose.

Adding extra dosing arms like this is a fairly common strategy in drug development, where it can be very difficult to predict what dose will be ideal, even if very detailed work is done in animals before going into humans. Sometimes it is necessary to keep increasing the dose, guided by some measure of success, until some hint of a problem is seen, then step back to the previous dose and test that in a bigger trial.

Testing a higher dose will help Wave find whether greater reductions in mutant huntingtin can be achieved, and whether doing so is safe. It may be necessary to go even higher, depending on what the results of the new 32 milligram dose show.

Wave has also added a 32 milligram dose to its other trial, PRECISION-HD1. Because of this, **the final results of both trials will now arrive later than initially planned, in late 2020**.



MUTANT, WILD-TYPE AND TOTAL

There's another complication to understanding these results: remember that the Wave drug is trying to lower the mutant form of the protein without reducing the wild-type form, whereas the Roche drug is expected to lower them both equally. So even if both drugs achieved the same degree of mutant huntingtin reduction, there is more happening behind the scenes that the headline 'mutant huntingtin' percentage doesn't tell us. We don't yet have any clear idea whether lowering wild-type huntingtin alongside the mutant form makes any difference, and until Roche's big trial completes, we are unlikely to find out.

To us, this is another reason to be cautiously pleased that a reduction in mutant huntingtin has been reported, and wait as patiently as we can for more information.

Talking of wild-type huntingtin – what can we say about whether Wave's drug succeeded in leaving it unaltered while lowering the mutant version? So far, not a lot!

For reasons to do with how awkward the protein is, we can measure the level of mutant huntingtin quite accurately, but there is no direct way of measuring how much wild-type huntingtin the spinal fluid contains. We **can** measure the **total** amount of huntingtin in spinal fluid – that's the combined pool of mutant and wild-type. When Wave did that, they found that the drug hadn't altered it.

That might seem weird - if they reduced mutant huntingtin by 12%, and didn't change the level of wild-type huntingtin, then surely the total level of protein should fall by 6%? Possibly - but every measurement has error in it, and simple assumptions like that might be built on shaky foundations.

What's certainly true is that with a small reduction in mutant huntingtin, it is very hard to say anything for sure about the drug's effects on wild-type protein. At this point, we don't think any conclusions can be drawn on that front. We need more information,

from more people, before we can start to understand the relationship between changes in mutant and total Huntingtin in the spinal fluid of HD patients in these studies.

LIFE'S COMPLICATED

One thing we've noticed in the wake of this announcement is a fair amount of speculation on social media and in the news. There seems to be a 'received wisdom' among investment folks that these results should be disappointing for Wave.

We don't really agree with that position, which seems to have come from an over-simplistic comparison of the headline percentages in mutant huntingtin reduction, and the potentially expensive addition of a new higher dose arm.

In fact, RG6042 went through exactly the same process when it was first tested in patients by Ionis Pharmaceuticals. Initially, four dosing levels were planned, but then a fifth, higher dose was added when the trial was already well underway. The main difference here is that Wave has announced their initial results at the same time as the decision to add another dosing arm.

Our advice here is – as ever – to take speculation in the news and especially on social media with a large pinch of salt. Try to get your information from many sources, and if things are confusing, it may well be because nobody knows the full answer.

As scientists driven by progress towards effective treatments for HD, we are interested above all in facts and data. Assuming Wave's announcement is an accurate reflection of the trial data, it represents an important milestone: for the first time, there are multiple drugs in the world that can lower mutant huntingtin in the spinal fluid of patients. Critically, we have drugs that target total Huntingtin, and others that target only mutant Huntingtin, allowing us to compare the risks and benefits of both approaches, in the only place that matters, which is HD patients.

Many questions remain unanswered, and for now we have to be OK with that. What's the best dose of

Wave's drugs? Will Wave's drugs slow progression of Huntington's disease? How will they compare with other huntingtin-lowering drugs? These questions will take much longer to answer, and we must be patient and determined to get the trials done and hope that clear answers will emerge. For now, we're cautiously pleased that 2020 has begun with a little ray of light.

Dr. Carroll has conducted sponsored pre-clinical research with Wave Life Sciences, but has no personal financial interest in the company. Dr. Wild served as an advisor to Wave Life Sciences before the launch of the PRECISION-1 and -2 studies, but he has played no role in the studies since their launch and has not financial interest in Wave Life Sciences. For more information about our disclosure policy see our FAQ...



All images sourced from Wave Life Sciences Corporate Presentation located on the Wave Life Sciences website: www.wavelifesciences.com

REGIONAL REPORTS

AUCKLAND & NORTHLAND



What's been happening....

Kia ora everyone!

2019 Was an exciting year for the Huntington's community, with the first Huntington's Disease gene therapy clinical trials emerging globally. It was also the Centre for Brain Research's 10th Anniversary with many events being held. We joined our patron the Distinguished Professor Faull in a two-day symposium, we also attended a Huia with the Taranaki whanau's, Distinguished Professor Faull and Waiora Port. We also had the pleasure of attending Professor Curtis lecture "Your Amazing Brain" which was one of the most amazing lectures I have attended.

Sir Richard Faull



Professor Maurice A Curtis



We have the pleasure of introducing Sue Poritt new nurse for the Regional Huntington's Disease service.

We held a very successful fundraiser movie night THANK YOU for everybody's support it was a great film with great people enjoying themselves.



We also had a night at the movies for all our Star Wars fans 'The force was strong that night' and a good time had by all.



Once again we joined in the festive session with many of our family whanau's and spread a little joy by doing what is important as per Goran Persson quote "We will be there for one another as fellow members of humanity, in the finest sense of the word".



From a financial view 2019 was also the most challenging yet, and we would not be here without the ongoing support of our non-paid members so thank you to all of you and for all your support.

A very special thank you must go to the Freemasons and to our Christchurch Association your generosity and kindness has help so many we do not have words to express the gratitude from our families/Whanau's but please know that together we make such a different to our committee.

We are look forward to a more financial stable 2020 and to a positive year full of updates on research, and developments in clinical treatments.

- Jo

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WAIKATO



Kia ora and Welcome from the Mighty Waikato!

Happy New Year Everyone. I hope you have had a great start to the new decade and are coping with the extreme heat we are currently experiencing. Please remember to keep hydrated and remind your family members to drink plenty, as we know, those impacted by HD can have difficulty recognising thirst.

Looking ahead this year we are currently in the planning phases for an HD Family Day Out and also a Carer's Day later in the year. The HD clinic established last year at WDHB Neurology department continues to run smoothly and enhances the services we provide to our HD community.

Looking back on last year, 2019 ended on a high note here in the Waikato with our annual HD Education Evening. Our HD community filled the room to listen to Neurologist Matt Phillips present "HD Therapies, Past, Present and Future". Starting with a brief history of HD, he then discussed present medications prescribed to treat the various symptoms. Matt noted that many of the medications only mask symptoms and often counterproductive side effects are experienced. Not satisfied with this, Matt leans on a quote by Carl Sagan; "Imagination will often carry us to worlds that never were, but without it we go... nowhere"... that helped him to think outside the square to the metabolic realms of treatment.

Matt has already undertaken study projects with other neurological diseases, Parkinson's, Alzheimer's and Epilepsy, to see how symptoms improve when participants are consuming a Ketogenic diet. The results in these studies have been significant enough for him to believe it could

be a potential pathway towards a cure for HD. Many of the research studies currently underway focus only on one part of the pathological process; however, Matt believes the ketogenic diet may have the ability to repair multiple damaging processes in HD.

Currently there are HD animal studies trialling the ketogenic diet, but Matt is interested in human studies to understand the benefits. If you are interested in **participating in a six-month research study of a ketogenic diet designed for HD commencing this year**, contact Dr Matt Phillips at: matthew.phillips@waikatodhb.health.nz

- Tracey

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HAWKES BAY

What's been happening....



Tēnā koutou, tēnā koutou, tēnā koutou katoa!

As I write to you from Hawkes Bay on Waitangi day, I thought it appropriate to reflect on the Maori word whanaungatanga meaning 'relationship, kinship, sense of family connection - a relationship through shared experiences and working together which provides people with a sense of belonging. It develops as a result of kinship rights and obligations, which also serve to strengthen each member of the kin group. It also extends to others to whom one develops a close familial, friendship or reciprocal relationship'.¹

I sense that this is a valid description of the comradery and support that is expressed when HD families and friends gather and the importance of social connectivity.

So we have gathered for two further afternoon occasions since the last newsletter, one at a Hastings café for scones and coffee and the other was high tea set amongst the lavender field in a local Taradale farmlet in December. After munching our way through hot savouries, scones, slices and cake accompanied by tea, coffee or sparkling grape juice, Elizabeth Hewitt from Roche gave an update on the latest HD research being undertaken. Libby was able to answer questions in this relaxed setting and many people took the opportunity to also speak

with her one on one. Libby is scheduled to return to Hawkes Bay next month for a meeting which I am attending with one of the local Neurologists. Once replete from our high tea, we were invited on a walking tour of the farmlet, which is off grid and aims to be as environmentally friendly as possible. I think quite a few people visited the farms shop and went home with free range eggs and lavender products to enjoy.



Suitable accommodation options continue to be the main challenge in this region for those requiring residential care, with one person needing transfer outside of the district, which causes emotional and financial strain for those involved. Wet area bathrooms become of crucial importance when securing appropriate housing and this requirement has caused considerable delay for some. Obtaining funding and approval to modify housing is not a process for the faint hearted!

The weeds in my garden are beckoning so I am about to slip, slop, slap before venturing out in to the heat.

Haere rā

- Jocelyn Pack, RN

Huntingtons Disease Advisor

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¹Te Aka Māori-English, English-Māori Dictionary and Index. 3rd edition, 2011. Longman Pearson Education New Zealand.

TARANAKI, WHANGANUI & MANAWATU



Kia ora everybody,

2020 is underway and so is our summer, somewhat belatedly it seems in my region. A few sunny days strung together can certainly lift spirits but too much heat can have the opposite effect. I'm only just getting into that summer mode feeling and now I'm back on the job, I hope it stays for a while longer.

The beginning of the year is often a time for setting goals and I'm aware of several people undertaking exercise goals to improve their energy levels, balance and strength. Feeling more in control from an exercise mood boost is also spoken of. Walking the dog which is what I do has the benefit of making your companion happy and giving yourself some meaningful exercise in the process.

Consider joining a walking or other type of exercise group for it's social benefits too. Exercise can be large or small, it's all about feeling better doing it or having done it. livestronger.org.nz is a good website for finding a variety of exercise groups to choose from in your area.

Getting out into nature has beneficial effects according to various research findings, so get out to visit a park near you, regularly, if you can. The Japanese have a word Shinrin-yoku which translates to "bathing in the forest." It's not about exercise, it's simply being in nature and connecting through sight, hearing, smell etc. I'm sure bathing in a park comes close or even a garden.

I can help clients and families by providing information, support and understanding of Huntington's. If you would like a visit or conversation please contact me.

Thank you for your trust in my role for the Wellington HD Association. I look to keep providing you with a useful service.

Best wishes for the year ahead,

- Karen

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WELLINGTON

What's been happening....

Kia ora everyone!

Already February of a new year. I hope you all had a good Christmas and holiday. It was lovely to see many family members from different parts of the country at the Amaryllis House Christmas lunch in December.

It was a nice sunny day and the staff did such a good job of preparing a wonderful lunch for us all. It is great that residents have such support and they all enjoyed the day. Summer in Wellington has not been great which is disappointing for us all. Our clients in Greytown and Nelson have probably been a little luckier with the sun!

We start our year with our first committee meeting next week and we will again be looking at fundraising and how to maximize our applications - a challenge for all in the sector.

Hopefully fresh ideas from the committee might help with what is an ever present challenge. The end of 2019 was busy with housing, employment issues and the ongoing difficulties for people in accessing the care and support they are eligible for. Nothing in these days of bureaucracy is simple and all our roles have many complexities in achieving the best outcomes for clients.

We all look forward to hearing of new advances in the field of research and potential treatment and 2020 will be very exciting for us in this respect. I will be catching up with everybody early in the year and look forward to seeing you soon.

- Jeanette

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CHRISTCHURCH

Greetings from Christchurch,

Well Christmas has come and gone with most people back to work and holidays just a distant memory. I hope that however you spent this time that you had the chance to relax, catch up with family and friends and recharge your batteries for another full on HD year.

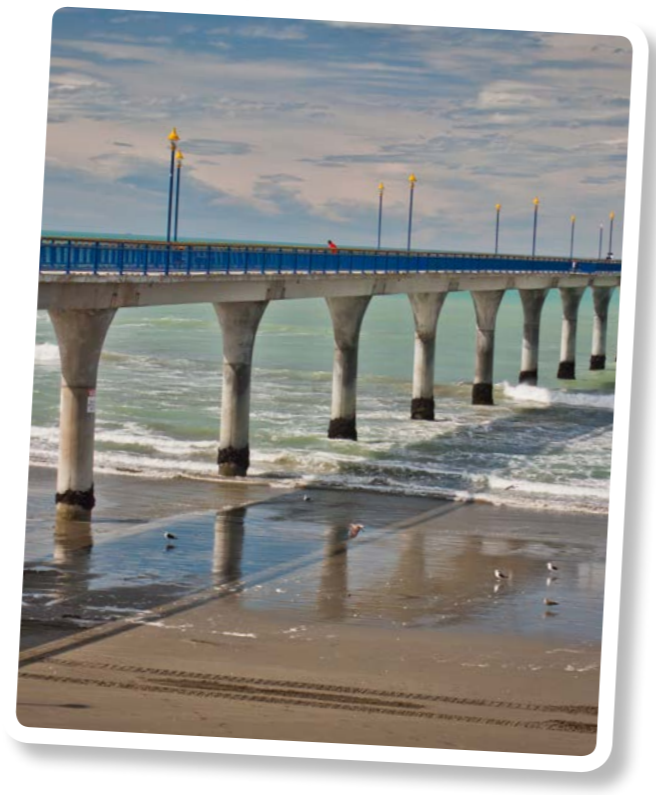


Emotions are starting to build for the people of Christchurch as we remember the events that unfolded on March 15th last year. It makes you stop for a moment and be grateful for the wonderful opportunities we have living in such a beautiful country like New Zealand.

The people of Christchurch sent out a strong message in the days and weeks that followed and I believe it has made us all a little stronger, more accepting and hopefully more understanding. Kia Kaha – Stay strong.

The Christchurch HD Association helped and supported families in the lead up to Christmas with the help of Maggie Jury identifying what the needs were out there within our HD community.

We as an association are only as good as our people on the ground. We are so thankful for the dedication, wisdom and 'can do attitude' that Maggie has to with our HD families, Maggie you



make a difference in so many life's and make what seems some days a huge mountain, you come along and chip away at it turning it into a slight rise – thank you Maggie.

Our thanks also goes out to our youth team, they are always available and ready to meet or chat with youth from not only our region but also extending as much help as they can to the youth around the South Island. Nothing is too much trouble for this team and they are always keen for the chance to meet up and chat. This is also extended to parents who may have concerns about young ones, don't hesitate to call on this team of HD experienced people.



What's been happening.....

We have held our first **Carer Support group** for 2020 with everyone busy talking about what they got up to over the Christmas period.

This is held the first Wednesday of every odd month. The dates for this year are as follows:

Wednesday 4th March - 6pm Papanui Club, Sawyers Arms Road

Wednesday 6th May - 6pm Papanui Club, Sawyers Arms Road

Wednesday 1st July - 6pm Papanui Club, Sawyers Arms Road

Wednesday 2nd September - 6pm Papanui Club, Sawyers Arms Road

Wednesday 4th November - 6pm Papanui Club, Sawyers Arms Road

Look out for the date of our Big Day Out this year, once we have firmed up the plans we will send out the details.

Well that's it from Christchurch, keep cool, keep hydrated and don't forget to slip, slop, slap!

- Dianne

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