



**SUPPORTING
– WOUNDED –
VETERANS**

**REHABILITATION
TO EMPLOYMENT**

Your donations will support research into
MDMA-assisted therapy: a revolutionary approach
for severe, treatment-resistant PTSD.

The Pioneer Programme:

a £1.5m appeal to help us transform
the treatment of Post-Traumatic Stress
Disorder (PTSD) in the UK

“

To have the chance of a new life.
To have a world where my PTSD is not
as dominating as it is right now. To put
the past into some sort of context
and not be haunted by it every day,
every moment in the future.

What a wonderful gift that would be.”



I know many former servicemen and women who suffer from mental health injuries, many of whom are extremely high performing individuals. Their injury is preventing them from achieving what they wanted in life.”

Martin Hewitt
Ex-Para and SWV Ambassador

Our challenge...

For too many of our veterans, the real battle begins when they return home.

Nine per cent of ex-regular servicemen and women who had deployed to Iraq or Afghanistan suffer from Post-Traumatic Stress Disorder or PTSD. For those whose last deployment was in a combat role this rises to 17%¹.

PTSD can affect anyone. Within the civilian population the rate is 4.4%². Early evidence from the COVID-19 pandemic is showing that 20% of Intensive Care Unit survivors could develop this debilitating condition³.

Sadly, veterans with PTSD are not getting the care they need. Existing therapies, like Cognitive Behavioural Therapy, only offer a modest, 30% chance of success. Veterans fare worse from existing treatments and have tried every therapy and every possible medication. They have come too close to giving-up on ever finding a solution to the devastating effects of PTSD on their lives and their families.

At Supporting Wounded Veterans (SWV), we know that veterans can embrace their full potential when they are free from the pain of physical and mental injuries.

Your support will pioneer revolutionary new research to enable a more effective treatment for all trauma survivors, including those affected by war, sexual assault, torture, rape and child abuse.

Supported by **NHS England**, we are working with world-class researchers in this pioneering field at the Institute of Psychiatry, Psychology & Neuroscience at **King's College London** to deliver the UK's first MDMA-assisted therapy trial committed to finding an effective treatment for the most severe PTSD.

Your financial support could be the answer to transforming their lives forever.



PTSD can affect any rank or role in the military. We've seen a significant increase in applications for SWV support from veterans with PTSD in the past five years.

We need to look at something that's new, that's revolutionary, to maximise the support for people being treated and healed from this injury.”

Martin Hewitt,
Ex-Para and SWV Ambassador

PTSD can happen to anyone

- PTSD can be caused by war, sexual assault, childhood abuse, torture, accidents and other traumatic events, like COVID-19 ICU survivors.
- It involves changes in the brain which decreases activity in the hippocampus and prefrontal cortex (areas associated with memory and learning) and increased activity in the amygdala (areas associated with fear).
- People who suffer from PTSD relive their traumatic experiences repeatedly. This can lead to insomnia, fractured relationships, inability to sustain a job, substance abuse, depression and suicide.



There is nothing left in the medicine cabinet. We've seen no new treatments since the development of the first antidepressants. We've all reached the same conclusion that psychedelic medicines are the best chance in the turning the dial for those who have been waiting too long for help."

Gilly Norton Founder & CEO
Supporting Wounded Veterans

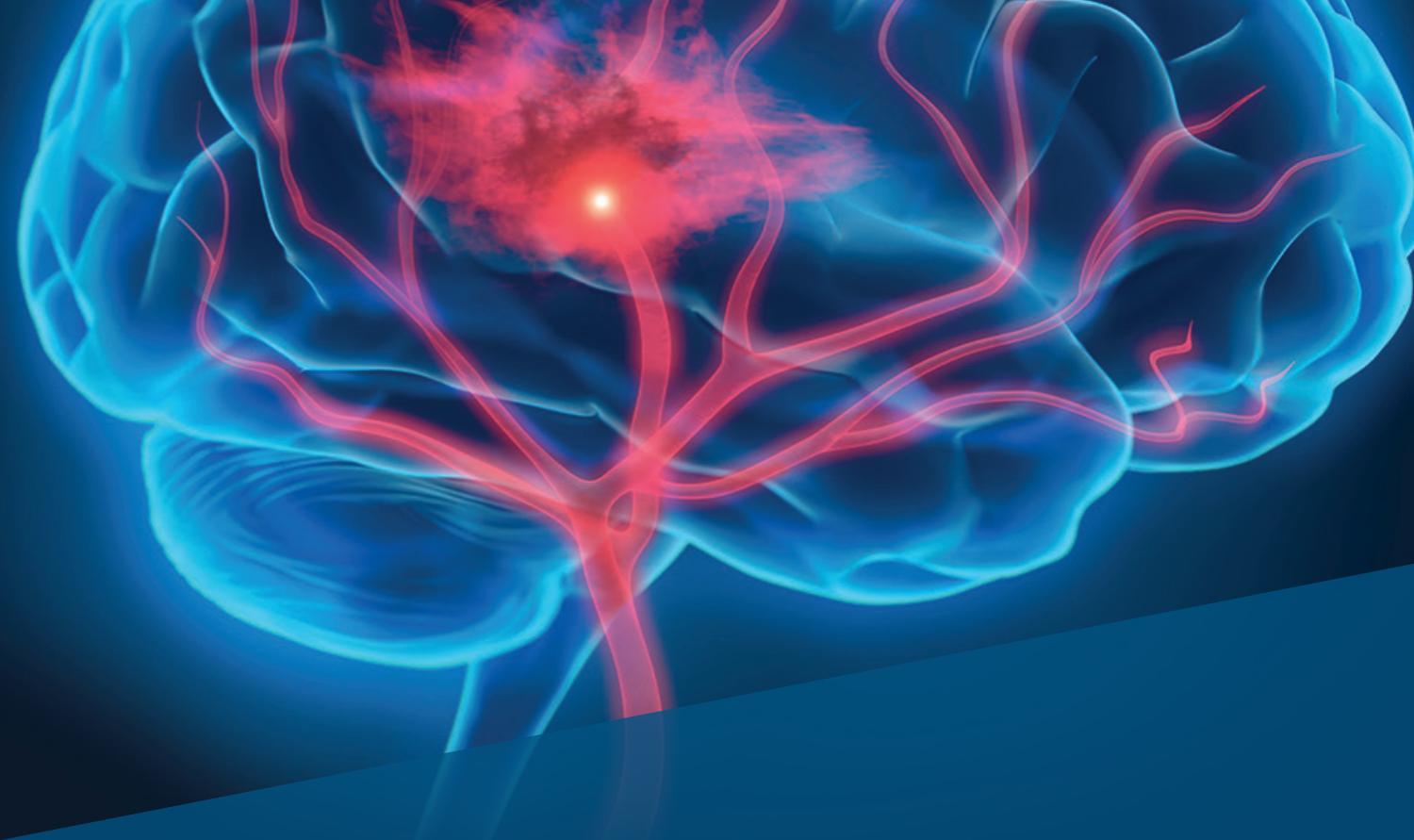
A revolutionary therapy offers hope

MDMA-assisted therapy

- MDMA-assisted psychotherapy involves the administration of carefully-controlled pharmaceutical-quality doses of MDMA in combination with a specialist form of trauma-focused psychotherapy. The treatment takes place under the guidance of highly accomplished clinicians and in a medically supervised setting.
- The aim of the treatment is to create the ideal conditions for effective trauma-focused psychotherapy by promoting neural plasticity and reducing the fear response. This supports study participants to overcome their trauma by helping them access their innate capacities for resilience and posttraumatic growth.
- The highly positive therapeutic impact is not due simply to the physiological effects of the medicine; rather, it is the result of an interaction between the effects of the medicine, the therapeutic setting, and the FDA-approved form of specialist psychotherapy employed.
- The treatment creates a unique window of optimal arousal that enables participants to revisit traumatic and distressing experiences without becoming overwhelmed. In an atmosphere of safety and acceptance, the treatment promotes feelings of empathy, openness, and self-compassion, as opposed to the shame and blame that many veterans experience, particularly when they're asked to talk about trauma.
- Clinicians and researchers at UCLA, Yale University, Johns Hopkins University and King's College and Imperial College in London have already led many psychedelic drug trials to research treatments for a wide range of debilitating mental health issues across addiction, eating disorders, anxiety, and depression.

MDMA

(3,4-methylenedioxy methamphetamine) is a psychedelic compound which enhances the effect of psychotherapy. It was invented by the Merck pharmaceutical company in 1912.



The MDMA floods the brain with serotonin, which quietens down the fear system in the brain that seems to be so overactive in PTSD, inducing a more general state of relaxation. It's this relaxed state that coupled with the support of a therapist allows patients with PTSD to re-experience their symptoms without being overwhelmed.

It allows them to see, often for the first time, that they can engage in therapy, sowing a seed that ongoing psychotherapy can nurture into post traumatic growth."

**Dr James Rucker,
King's College London**

We are here to break down barriers and make a difference

Why SWV?

Founded in 2012, SWV has helped hundreds and hundreds of wounded UK veterans find employment and independence through sport, pain management and mentoring.

Our approach supports the most vulnerable. By listening to them on their recovery journey we have learnt how pain and trauma has affected their ability to lead an independent life.

We started to help by offering sports recovery through skiing. Through the close bonds developed on our Sports Habilitation programme, we discovered that pain was the biggest barrier to veterans reaching their full potential.

This led us to commission innovative programmes within the NHS, including our Pain Review and Pain Management Programmes which give veterans the tools to manage their long-term and chronic pain. Combined with mentoring and peer support we help veterans to get their lives back on track.

As we continued to work with veterans and helped them to resolve their pain, we discovered that PTSD was another barrier to independence.

Together with **King's College London, NHS England** and **MAPS** (Multidisciplinary Association for Psychedelic Studies); and backed by our Patron, **General Sir Nick Carter**, the UK's first MDMA-assisted therapy trial could solve severe PTSD for good.

Solving treatment-resistant PTSD is the next battle to fight. We are confident that psychedelic medicines represent a real solution to a difficult problem.



“

There are lots of charities claiming to help but these guys really go the extra mile. Nothing has been too much trouble. Without these awesome people I dread to think where I would be.”

Veteran



PTSD is a truly debilitating and life-threatening battle – defeating it requires innovation. Studies of MDMA-assisted therapy in the US are proving it to be dramatically more effective than other treatments at relieving the pain and removing the stigma of PTSD.

We, and importantly, our veterans are convinced it merits further study and trial. Many of these veterans have made remarkable sacrifices on behalf of our country.”



This programme, driven by SWV, genuinely promises to make a difference to the lives of wounded veterans who deserve the chance to live normal lives.”

General Sir Nick Carter,
Chief of the Defence Staff
& SWV Patron

What is the Pioneer Programme

Our UK research aims to:

Evaluate the effectiveness of MDMA-assisted therapy as a treatment for severe PTSD in UK veterans by conducting two clinical trials:

- Phase 2 Lead-In study; and
- Phase 3 Trial of MDMA-assisted therapy.

Replicate US trials undertaken by MAPS, where Phase 3 trials are already demonstrating positive outcomes, with 67% of participants not qualifying for a PTSD diagnosis after three months.

Contribute to a European study across six countries to secure regulatory approval (European Medicines Agency (EMA) and Medical and Healthcare products Regulatory Agency (MHRA)) for a licence to be available for the treatment of all trauma survivors in the UK. This treatment will only be available in countries where a MAPS trial has taken place, making it vitally important that a trial is delivered in the UK.

Due to the EMA data exclusivity regime, if this research is only undertaken overseas, UK veterans and all civilian trauma survivors will have to wait at least eight years for the treatment to be available in the UK.

The UK trial will make up 35% of the European study, giving the opportunity to put UK specific trial data in front of the MHRA to seek approval for therapeutic roll-out in the UK (with the FDA already designating MDMA-assisted therapy a ‘Breakthrough Therapy’ in 2017).

UK results

With UK results expected to replicate the US, this trial will deliver a strong scientific case for this new therapeutic approach.

What does MDMA-assisted therapy involve?

- After informed consent, eligibility assessment and robust psychological preparation, participants are given MDMA under medically supervised conditions during a psychotherapy session at the Clinical Research Facility at KCL.
- MDMA-assisted sessions are 8 hours long, 2 (phase 2) or 3 (phase 3) times, scheduled 3-5 weeks apart in conjunction with 9 (phase 2) or 12 (phase 3) weekly 90-minute non-drug psychotherapy sessions.
- The UK trial of 25 veterans contributes to the European study of 70 participants. The focus of the research is on veterans who have not responded to, or are unable to engage with, current treatments.
- Phase 2 will include 6 veterans who will receive MDMA as part of the ‘lead in’ study to also act as a legal clinical supervision training for the therapists.
- Phase 3 will include 19 veterans, 50% of whom will receive a placebo.
- The study design ensures that all veterans who receive the placebo will receive the MDMA-assisted therapy option at the end of trial.

The story so far



2016

MAPS Phase 2 clinical trials of MDMA-assisted therapy included 107 patients with chronic PTSD. Within the group receiving psychotherapy with MDMA, 56% of subjects no longer met the diagnostic criteria for PTSD at the primary endpoint. At the one-year follow-up, 68% of all subjects treated with full-dose MDMA no longer met the diagnostic criteria for PTSD, demonstrating the durability of positive treatment outcomes and continued improvement over time.

2017

FDA designated MDMA-assisted therapy for PTSD a Breakthrough Therapy, indicating it is among the most promising treatments being developed.

2019

MAPS completed training certification for Phase 3 investigators and initiated the first Phase 3 trial at 15 sites across the United States, Canada and Israel. Results show that this therapy provided to patients with severe or extreme, chronic PTSD appears to be cost-saving while delivering substantial clinical benefit⁴.

2021

The randomized, blinded, Phase 3 trial treated 90 patients with severe PTSD. The primary efficacy endpoint was based on the change from baseline in an independently assessed clinical interview of PTSD severity after 18 weeks.

Among the participants in the MDMA-assisted therapy group, 67% no longer qualified for PTSD diagnosis after three MDMA-assisted therapy sessions and 88% of participants experienced a clinically significant reduction in symptoms.

Full results in Nature Medicine: <https://www.nature.com/articles/s41591-021-01336-3.pdf>⁵.

Investigators observed no serious safety or tolerability issues in the MDMA group. MDMA did not increase the risk of suicidal thoughts or behaviours and did not increase cardiovascular risk or abuse potential relative to therapy with placebo. Enrolment in the second planned trial (N=100) has begun.

Together, we are making progress



The research team is led by **Professor Allan Young and Dr James Rucker at the Centre for Affective Disorders at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London. The IoPPN has extensive experience in conducting clinical trials in PTSD and traumarelated conditions.**

Professor Allan Young (Chief Investigator) holds the Chair of Mood Disorders at King's College London where he is also Director of the Centre for Affective Disorders within the Department of Psychological Medicine in the Institute of Psychiatry.

Professor Young was recently ranked as one of the world's leading scientific minds in the field of Psychiatry and Psychology, according to the 2014 Thomson Reuters Highly Cited Researchers list. In all of science, a total of over 3,000 researchers worldwide earned this distinction and the academics listed rank among the top 1% most cited for their subject field and year of publication, a mark of exceptional impact.

Dr James Rucker (Principal Investigator) is an Honorary Consultant Psychiatrist and NIHR Clinician Scientist Fellow, specialising in mood disorders and psychopharmacology.

Dr Rucker completed his medical degree at University College London (UK) in 2003 before training in psychiatry at the Maudsley, Bethlem and Springfield Hospitals in South London. He completed his PhD in the molecular biology of mood disorders at King's College London in 2012.

Dr Rucker specialises in novel treatments in mood, anxiety and trauma response disorders and is particularly interested in the therapeutic interface of psychotherapy, psychopharmacology and society. He leads The Psychedelic Trials Group at King's College London, which undertake gold standard clinical trials of psilocybin and MDMA assisted therapy for treatment resistant mood, anxiety and post-traumatic stress disorders.

Therapy Team

King's College London have recruited and trained a group of 12 highly specialised and experienced therapists to support the veterans participating in the trials.

The therapists have completed the FDA approved MAPS MDMA-assisted therapy for PTSD Therapy Training Programme. This includes in-depth training into the practice of MDMA-assisted therapy for PTSD, with the curriculum based on decades of clinical experience. This specialised training builds competency for the conduct of this modality and ensures that practitioners offer the treatment in a safe, effective, and ethical manner.

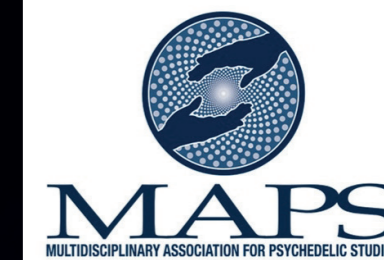
Research includes

2020

A comparison of MDMA-assisted psychotherapy to non-assisted psychotherapy in treatment-resistant PTSD: A systematic review and meta-analysis

2017

Psychiatry and the psychedelic drugs. Past, present and future.



MAPS is a US non-profit in the field of education and research. It has raised over \$100m to create a paradigm shift in mental health care through the medicalisation of psychedelic-assisted therapy.

Founded in 1986, MAPS is regarded internationally as the leading organisation for responsible research, education, harm reduction and advocacy in the field of psychedelic drug development.



UK Trials

2020

Pioneer Programme conceived by SWV with MAPS, King's College London and NHS England.

The protocol, Informed Consent Form and study documents have been reviewed, and received approvals from the NHS Research Ethics Committee (NREC) and MHRA. It will also follow ICH-GCP, EU Directive 2001/20/EC, US CFR Title 21 and the Declaration of Helsinki guidance.

2021

Therapist training begins. Participant enrolment to open. Fundraising appeal for £1.5m goes live.

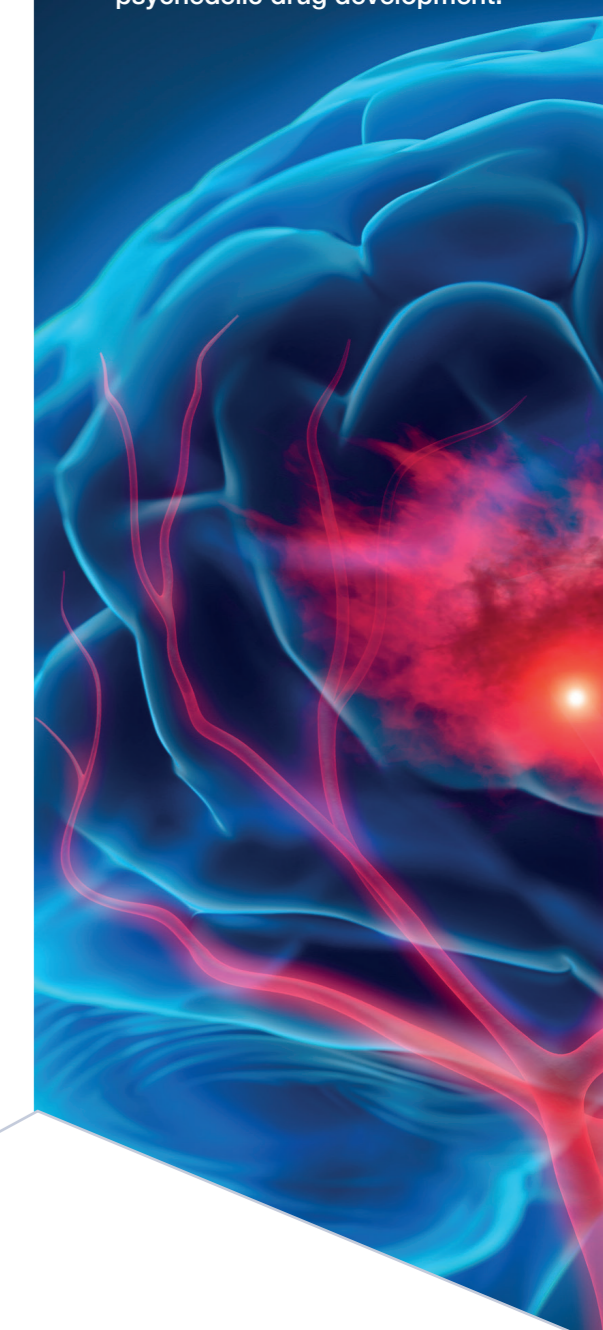
2021-22

UK Trials begin (N=25) as part of MAPS third Phase 3 trial conducted under the regulatory guidance of the EMA (N=70). The Phase 3 trials are randomised, blinded, placebo-controlled studies.

2023-24

Applications for licence approvals to MHRA and EMA, with Market Authorisation applications for two products: MDMA by prescription and MDMA-assisted therapy certification. MDMA will only be administered under clinical supervision and will not be available as a take-home medication.

Scale-up of training and treatment centres to roll-out of treatment for UK veterans and all trauma survivors.



How your donations will be used

The total cost to deliver the Phase 2 and Phase 3 Pioneer Programme in the UK is £1.5m.

To kick-start the programme, SWV has committed £100,000 to the fundraising appeal.

With thanks to our Pioneering partners, including NHS England and MAPS, we have raised £775,000 of the £1.5m costs.

We are now seeking to raise the final £725,000 to commence the trial and pioneer this treatment for the benefit of all trauma survivors.

With 4.4% of the civilian population with PTSD in England, MDMA-assisted therapy will be a game-changer in this complex and difficult field, reducing the long-term, and repeated, costs of care for those with PTSD.

There is a significant social and economic cost of PTSD on those with the condition and their families. For every life lost to suicide, the estimated total cost to the economy is £1.7m.

Once approved **we expect this treatment to be available for c. £10,000** per patient. This makes it more cost-effective than existing, and often repeated, in-patient admissions at £25,000 for three months in addition to the societal costs associated with the illness.

| Budget (£) | |
|----------------------------------|------------------|
| Research framework and protocols | 264,100 |
| Treatment – therapy and drugs | 532,197 |
| Facilities | 18,362 |
| Therapist training | 142,691 |
| Regulation, legal and reporting | 343,538 |
| Contingency | 94,255 |
| VAT | 105,842 |
| Total expenditure | 1,500,985 |



“

I am looking forward to immersing myself into a new treatment so I can be the best version of myself. I have often wondered what it might be like to have some sort of recovery. It's really emotional to think that I can unburden myself from some of these chains that hold me back.

For my PTSD to be alleviated through this treatment would be priceless.”

Veteran

References

1. Mental Health of the UK Armed Forces, King's Centre for Military Health Research, September 2018.
2. Mental Health and Wellbeing in England Adult Psychiatric Morbidity Survey 2014, NHS
3. 'COVID-19: National PTSD screening programme urgently needed', COVID Trauma Response Working Group, UCL, June 2020.
4. Marseille: The cost-effectiveness of MDMA-assisted psychotherapy for the treatment of chronic, treatment-resistant PTSD, 2020.
5. MDMA-assisted therapy for severe PTSD: a randomised, double-blind, placebo-controlled phase 3 study, Nature Medicine, May 2020, <https://www.nature.com/articles/s41591-021-01336-3.pdf>

With your help we can go all the way

Once the trials have been delivered and the treatments are approved, our long-term aspiration is to support a sustainable roll-out of MDMA-assisted therapy for PTSD to the veteran population.

Broad estimates suggest that there are c. 300,000 veterans in the UK with PTSD, with thousands more suffering in the civilian population amidst a global pandemic, conflict, trafficking and pervasive sexual violence.

As a military charity we are focused on the veteran outcomes of this treatment as they tend to fare worse than civilians in existing treatments. However, for the enduring benefit of all trauma survivors we must lead and fund this work now.

We estimate over five years that we could help 2,500 of those veterans who have been failed by existing treatments. To do this we would develop a new Centre of Excellence for Psychedelic Medicine in conjunction with a certified therapist training programme.

We have also brought together 38 of the leading, global military psychiatrists to work together to share their broad knowledge of psychedelic medicines to help shape the future treatment pathways for veterans.

With King's College London, the NHS, military charities and others within the psychedelic medicine community we are discussing the opportunity to establish a physical Centre of Excellence for therapists to deliver this treatment in-person for the thousands of veterans with PTSD in the UK.

Please call...

Gilly Norton (07710 485668) or **Jenni Anderson (07949 031539)** to discuss this exciting opportunity to bring solace to thousands of people with PTSD.

We expect a tsunami of people will want, and deserve, this treatment.

The Pioneer Programme
Supporting Wounded Veterans

You can make a real difference to those who have made a difference for us.



**SUPPORTING
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**REHABILITATION
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To find out more or to make a donation go to supportingwoundedveterans.com/pioneerdonation or email at jenni@swv.org.uk. You can make a real difference to those who have made a difference for us.

Join Us

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