

Sheba's HeraBEAT telemedicine clinical trial completed with excellent results

- Just-released results from a clinical trial undertaken by Israel's Sheba Medical Center conclude that the HeraBEAT smart fetal HR monitor is accurate and contributed to the effectiveness of maternal-fetal Telemedicine.
- The low-risk pregnant mothers who participated in the study went through an observation telemedicine visit using the novel HeraBEAT self-operated fetal HR monitoring technology while data were being remotely reviewed via the HeraCARE platform.
- The study found that remote telemedicine fetal well-being assessment, which included the usage of the HeraBEAT, is feasible and time-saving.
- In another clear positive, the study also found that these telemedicine consultations delivered high levels of patient satisfaction.

HeraMED Limited (ASX:HMD) ("HeraMED" or the "Company"), a medical data and technology company leading the digital transformation of maternity care, is pleased to announce the results of a study undertaken by Israel's largest hospital, the Sheba Medical Center, which has been Newsweek Top 10 ranked world's best hospital for the last four years. The study found that remote telemedicine monitoring delivers high-quality, reliable, and accurate vital signs measurements of both the expectant mother and fetus.

A link to the study, titled '*Novel Remote Fetal Wellbeing Assessment: Feasible, Time-saving and Associated With High Patient Satisfaction - A Prospective Pilot Study*', follows:

<https://fetalmedicine.org/abstracts/2022/var/pdf/abstracts/2022/04211.pdf>

HeraMED technology solves earlier limitations of telemedicine

The effectiveness of remote telemedicine monitoring has, until more recently, been restricted by technological constraints. Such consultations were limited to maternal assessment consisting of a video call with an obstetrician and maternal vital signs measurements. The delivery of high-quality, reliable, and accurate vital signs measurement of both mother and fetus remained elusive.

The Sheba Medical Center undertook a study, led by Dr Avi Tsur MD, Director of the Sheba Women's Health Innovation Center and of OBGYN Beyond, to determine the feasibility of extending remote pregnancy capabilities in the wake of innovative medical technology now available.

The test patients in the study were full-term low-risk pregnant participants. They went through an observation telemedicine visit using the novel HeraBEAT self-operated fetal monitoring technology. During this telemedicine visit, data, including non-stress test fetal monitoring generated by the HeraBEAT, as well as additional parameters, were obtained to assess a "modified biophysical profile" (BPP).

The length of test patients' visits was measured and compared for both the in-person first visit and the subsequent telemedicine encounter.

As part of the study, a patient satisfaction survey form was also filled out by study participants, based on a prescribed set of so-called 'Six Simple Questions' ('SSQ').

Key parameters and outcomes from the study

The study comprised ten patients, nine of which were able to complete remote modified biophysical profile assessments. These participants were recruited at the time of their first full-term in-person visit and scheduled for an observation telemedicine visit using the novel self-operated fetal monitoring specifically, HeraMED's HeraBEAT smart Fetal HR monitor.

Importantly, among the nine women completing the remote assessment, one was referred for additional assessment in the delivery room due to non-reactive fetal heart rate and lack of fetal body movements.

Telemedicine encounter length was measured at 93.1 ± 33.1 minutes, significantly shorter than the in-person visit 247.2 ± 104.7 minutes, $p < 0.01$.

This is a 60% reduction on average, potentially saving over 2.5 hours for both patients and, more importantly, the already stressed medical staff.

The completed 'Six Simple Questions' questionnaires indicated high patient satisfaction with the remote care assessment.

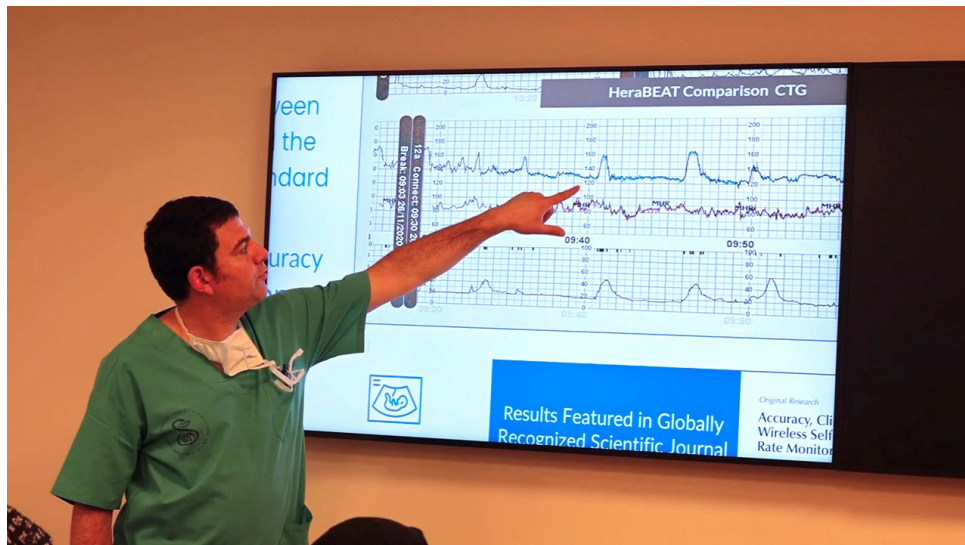


Figure 1: Dr Avi Tsur, director of the Sheba Women's Health Innovation Center and of OBGYN Beyond, lead researcher of the clinical trial evaluating the results

The study showed clear-cut benefits from telemedicine assessments

The study concluded that remote telemedicine fetal well-being assessment, combining a self-operated fetal heart rate monitoring device and a self-operated ultrasound device, is feasible, timesaving, and results in high levels of patient satisfaction.

It also found that the novel paradigm of comprehensive remote maternal and fetal assessment resulted in important clinical, economic, social, and logistics advantages.

HeraMED CEO and Co-founder, Mr. David Groberman said: “We are excited by the results coming out of this Sheba study, which indicate, once again, that our fetal and maternal heart rate monitor HeraBEAT is helping break down the technology barriers previously precluding the delivery of effective remote telemedicine monitoring for expectant mothers. The results are a clear positive for medical professionals worldwide looking for ways to deliver improved healthcare services. It was also pleasing to see that pregnant women in the study were very positive about their telemedicine experience. An added bonus in the current environment is that the remote monitoring functionality provided by HeraBEAT also helps limit the spread of the COVID-19 pandemic amongst expectant mothers.

This is the fourth consecutive clinical trial validating the high quality of our technology’s as well as its accuracy and effectiveness. These outstanding results reflect both the quality of our technology platform and, I am proud to say, the continued commitment of HeraMED’s dedicated and professional team. Without them the successful outcomes being delivered in these trials would not have occurred.

We look forward to continuing our efforts and focusing on the commercialization of our breakthrough technology, with the tailwinds of such clinical validation coming from leading healthcare providers worldwide.”

Lead researcher, Director of the Sheba Women's Health Innovation Center and of OBGYN Beyond, Dr. Avi Tsur MD said:“Our goal was to put the F (fetus) back in maternal-fetal telemedicine. Now that we are able to provide comprehensive remote assessment of both the mother and the fetus, the sky is the limit for the paradigm shift that will follow.”

About Sheba Medical Center

The largest and most comprehensive medical center in the Middle East, Sheba Medical Center, Tel Hashomer is generating global impact through its medical care, research and healthcare transformation. Sheba’s City of Health boasts an acute-care hospital, rehabilitation hospital, research and innovation hubs, medical simulation center, as well as a center for humanitarian disaster response on one comprehensive campus in the heart of Israel. Sheba serves as a true hospital without borders, welcoming patients and healthcare professionals from all over the world and consistently providing the highest-level medical care to all in need. Sheba has been ranked a Top 10 hospital in the world by Newsweek four years in a row (2019, 2020, 2021, 2022).

-ENDS-

This announcement has been authorised by the Board of HeraMED Limited.

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About HeraMED Limited (ASX:HMD):

HeraMED is an innovative medical data and technology company leading the digital transformation of maternity care by revolutionising the prenatal and postpartum experience with its hybrid maternity care platform. HeraMED offers a proprietary platform that utilises hardware and software to reshape the Doctor/Patient relationship using its clinically validated in-home foetal and maternal heart rate monitor, HeraBEAT, cloud computing, artificial intelligence and big data.

About HeraCARE™

The Company's proprietary offering, HeraCARE, has been engineered to offer a fully integrated maternal health ecosystem designed to deliver better care at a lower cost, ensure expectant mothers are engaged, informed and well-supported, allow healthcare professionals to provide the highest quality care and enable early detection and prevention of potential risks.

About HeraBEAT™

HeraBEAT is HeraMED's first medically accurate, scientifically optimized, smartphone-based fetal heart rate monitor for home use. It empowers expectant mothers to monitor their fetus' heartbeat anytime, anywhere. Enabling seamless data sharing of fetus' vital signs with medical professionals, parents can rest assured that their fetus is receiving the medical attention needed while they take their time to focus on the health of and the bond with their unborn child. Designed from the ground up to be used by the expecting mother, HeraBEAT™ integrates state-of-the-art technology and professional accuracy with a simple, straightforward user interface and a distinctive design into a safe, reliable, and affordable solution.