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NEWS LETTER
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Certain Conditions Can Impact How Much Exercise You Need To Ease Depression, Study Finds

As little as 20 minutes of moderate activity a day for five days a week can significantly lower the risk of depressive symptoms for people over 50 who have conditions often linked to depression, such as diabetes, heart disease and chronic pain, a new study found. People with diabetes have twice the risk for depression, according to Diabetes UK, and a 2017 study found heart disease patients are twice as likely to die if they develop depression after their diagnosis. Up to 85% of people with chronic pain experience severe depression, according to a different 2017 study. People without chronic disease in the study, however, needed to do moderate to vigorous exercise two hours a day to see improvement in depressive symptoms, according to lead study author Eamon Laird, a researcher at the Physical Activity for Health Research Centre at the University of Limerick in Ireland. Moderate physical activity is typically defined as an activity that "takes your breath" so that it is hard to speak while doing it. Examples include brisk walking, bicycling, dancing, playing tennis, or running up and down stairs. If the exercise level is increased to vigorous — such as jogging or running, during which breathing is fast and the heart rate rises — the time spent exercising can be reduced, according to the US Centers for Disease Control and Prevention.

"What is unique (about this study) that it is the first and largest investigation of a longitudinal cohort — with and without chronic disease — to try and work out what was the lowest minimal dose to observe a difference in depression," Laird said. "We do not advocate for reduced activity levels in any population, but these findings suggest that even doses lower than recommended may well protect mental health over time in older adults," he added. "These doses may be more achievable as many older adults may find it difficult to undertake physical activity for a large number of reasons."

A 10-year study

The study, published Monday in the journal JAMA Network Open, followed more than 4,000 Irish adults with an average age of 61 for 10 years. The participants, who were part of the Irish Longitudinal Study on Ageing, were evaluated every two years. They were asked about their physical activity and exercise levels and given tests to determine the number of depressive symptoms they displayed — if the symptoms were excessive, they were classified as having major depression. "Examples of symptoms from the questionnaire included: I had trouble keeping my mind on what I was doing; My sleep was restless; I felt I could not shake off the blues even with the help from my family and friends; etc," Laird said in an email. People who had suffered a major depressive episode during the past 12 months were also put into the major depression group. An episode is defined as a period of two weeks or longer in which the person experienced fatigue, feelings of sadness and hopelessness, a loss of interest in activities or sleeping problems, weight gain or loss, or thoughts of suicide.

The study found that the more time people spent exercising, the better. People who moderately exercised for 20 minutes a day, five days a week, had a 16% lower rate of depressive symptoms and a 43% lower risk of major depression compared with those who did not exercise, the study said. Those who exercised two hours day benefitted the most, with a 23% reduction in depressive symptoms and a 49% lower risk of major depression, according to the study. "The higher the physical activity dose, the greater the mental health benefits for depression," Larid said. Unfortunately, the overall rate of depression for the entire group rose over the 10 years, from an average of 8% to 12%, while antidepressant use increased from about 6% to 10%. However, rates of exercise also declined about 10% for the group over the study's duration.

Not a surprise

The study's finding were not surprising, Larid said, noting extensive past research that shows a strong link between exercise and reducing depression. A systematic review and meta-analysis published in 2022 found brisk walking for just 2.5 hours a week cut depressive symptoms by 25%. The same study also found that doing half that amount lowered risk of depression by 18%. Another large review published in February found that getting physical is 1.5 times more effective at reducing stress, anxiety and mild-to-moderate symptoms of depression than antidepressant medications or cognitive behavior therapy, which is considered a gold standard treatment. Exercise does more for a person's health than just ease depression. It keeps the body in tip-top shape, allowing it to function efficiently and do a better job at warding off disease of all kinds. "Physical activity is just absolutely magnificent," Dr. Andrew Freeman, director of cardiovascular prevention and wellness at National Jewish Health in Denver, Colorado, told CNN in a prior interview. "If you blend that with eating a more plant-based diet, de-stressing, sleeping enough and connecting with others — that's your magic recipe," he added. "It's the fountain of youth, if you will." (Source:CNN)

G20 Offers Immense Potential For Indian Pharma Industry: Pharmexcil Chief

The Indian Pharma industry can seek greater synergy among the G20 countries as it holds the presidency of the premier forum for international economic cooperation, said D-G of Pharmexcil. "There is a greater scope for mutual collaborations, which can result in a major push for exports. G20 countries are among the key export destinations for Indian Pharma exports," R Uday Bhaksar, Director-General, Pharmaceuticals Export Promotion Council of India (Pharmexcil) told businessline.

Out of India's total pharma exports of $25.4 billion, G20 countries accounted for $17.2 billion in FY23. Excluding the US and European Union (without France, Italy and Germany), highest exports from India went to South Africa ($657 million), followed by Brazil ($642 million) and Russia ($573 million).

Pharmexcil has been making special efforts to harness greater potential in South Africa, Brazil and Mexico in the recent past. According to a director of a Hyderabad based major drug-maker, there is a need to have greater regulatory convergence between European Union and markets like South Africa, and protocols have to be developed for value based products.

International Pharma Exhibition

The 9th edition of International Pharma Exhibition (IPHEX), a flagship event of the Pharmexcil, is being organised in Hyderabad from July 5 to July 7. The Ministry of Commerce and Industry is planning to use the IPHEX to tap into unexplored potential of G20 members in the pharmaceuticals sector. "The experts participating in the meeting are likely to provide some inputs on how to enrich the existing industry linkages between India and G20 nations, with special reference to exports of pharmaceuticals," Bhaskar said. IPHEX will also witness an exclusive G20 focused CEOs Round Table, with participation of delegates from about 100 countries. (Source: Business Line)

Indian Pharma To Reach $57 b By FY25: Report

The Indian pharma, which has a strong footprint in the generics segment grew by nearly 5 per cent on a y-o-y basis to $49.78 billion in FY23, and is expected to reach $57 billion by FY25, according to the CareEdge report. During FY18–FY23, the sector, including domestic and exports, registered a compound annual growth rate (CAGR) of 6–8 per cent with 8 per cent growth in exports and 6 per cent growth in the domestic market during the same period.

Compared to FY22, exports grew by just 3 per cent while the domestic market continued to grow at a healthy rate of 7 per cent in FY23.

Key developments

Pharma exports largely include formulation products, and with increasing focus on the synthesis segment, complex and specialty products, apart from the easing of pricing pressure in US generics, are likely to support growth in the medium term.

The US holds a prominent position as one of the largest export destinations for the Indian pharma industry, accounting for approximately 30–35 per cent of total formulation exports. In FY23, formulation exports to the US recorded a growth rate of 5.9 per cent, primarily supported by sales volume growth of around 16 per cent.

Furthermore, the pricing erosion in the US generic market has eased to low single digits, a significant improvement compared to the high double-digit erosion witnessed in the past two years.

Favourable landscape ahead

Looking ahead, approximately $188 billion worth of drugs worldwide are set to go off-patent during the period from CY2023 to CY2026, presenting a favourable landscape for the Indian pharma industry to capitalise on these patent expirations and expand its market share. CareEdge estimates the industry to grow at 7 to 8 per cent in FY24–FY25, supported by 6 to 7 per cent growth in exports and 8 to 9 per cent growth in the domestic market during the same period.

While the operating margin of industry players are expected to improve by 100–150 bps over FY24–FY25 compared to FY23, factors such as raw material prices, freight rates, and the easing of pricing pressure in the US generics market along with a focus on complex and specialty products. Furthermore, historically, the credit profile of Indian pharmaceuticals companies in general has remained stable due to their strong profitability and lower reliance on debt which is likely to continue. (Source Business Line)

Britain Celebrates 75 Years Of Its National Health Service

Britain on Wednesday celebrates 75 years of its National Health Service (NHS), with royals, politicians, staff and patients expressing pride in its past and determination that it will endure in the future despite current challenges.

Launched on July 5, 1948, by a Labour government following the Second World War, its mission was to ensure "everybody, irrespective of means, age, sex or occupation shall have equal opportunity to benefit from the best and most up-to-date medical and allied services available."

One former minister once remarked that the NHS was the closest thing the English have to a religion, such is the widely-held affection for the service and those who work for it. "For 75 years, the NHS has existed for an enduring moral purpose: To give every single person in our country the security that comes from knowing that if you're sick, you will be cared for," Prime Minister Rishi Sunak said in a speech last week.

But in recent years, the NHS has found itself needing emergency care, struggling to keep up with patient demands, an increasingly elderly and sickly population, and the cost of new medicines and treatments. The COVID-19 pandemic added another layer of strain onto an already creaking system, and the commemorations come after a winter of crisis followed by strikes over pay by junior doctors, nurses and healthcare workers. While some workers have now accepted pay offers, senior doctors have also recently voted for walkouts.

A COMFORT BLANKET

Sunak has said that one of his goals is to cut waiting lists, and last week the NHS set out a new long-term workforce plan aimed at securing the service for the future. On Wednesday, political and health leaders will gather for a service at Westminster Abbey, while King Charles has commemorated the event in Scotland. His son William hosted a tea party for staff and patients. "Wishing everyone a very happy 75th birthday of the NHS," William said, and his wife Kate added: "thank you so much for all you do."

Among those invited was Aneira Thomas, who was the first baby born on the NHS and was named after its founder, health minister Aneurin Bevan. She was born at a minute past midnight on July 5, 1948. "It was a turning point in history for the health of Great Britain," she said, adding that the NHS had saved the life of both of her children after brain haemorrhages. "After the horrors of the war, Great Britain was broken. So to have a National Health Service come into fruition, was like throwing a comfort blanket around the people of Great Britain." (Source: Reuters)

Drug Makers Step On It To Meet August 1 Deadline To Sport Bar/ QR Codes

With just days to go for the Centre's deadline requiring barcodes or quick response (QR) codes on 300 medicine brands, a lion's share of the companies owning these brands are working towards meeting the August 1 deadline, say officials familiar with the development. About 57 companies are expected to meet the Phase-I deadline, going by the activity on the ground, S. Swaminathan, Chief Executive Officer of GS1 India, a global standards organisation, told businessline. While about 90 per cent of the companies covered in the first leg look set to meet the deadline, the remaining are companies that import their products. GS1 has been set up by the Commerce Ministry, industry bodies and the Bureau of Indian Standards, to outline global standards that facilitate transfer of product information. It is an affiliate of GS1 Global.

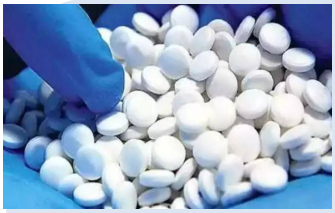
Centre diktat

The Centre had in November 2022 listed 300 top brands, including Allegra, Augmentin, Becosules, Betadine, Calpol, Dolo, Dexorange,Electral, Gelusil, Glycomet, Mixtard, Mox, Neurobion, Thyronorm and Volini, to name a few. These brands were required to sport bar/ QR codes to keep out fakes, by providing consumers information on the drugs. Medical devices are next on the cards, an industry representative said. Outlining the benefits, Swaminathan said, companies would be able to track their products and identify and recall drugs if the supply chain was compromised. The system will also have a trail of ingredients going into the drug and the distribution chain involved in getting the drug to the consumer, he added. The initiative comes even as allegations of contaminated cough syrup, and its possible links to deaths are reported overseas. While the Centre has been bringing out measures to ensure quality products leave Indian shores, industry-watchers sought stringent measures for products sold locally, as well. A joint study last year by GS1 and the Association of Healthcare Providers of India (AHPI) revealed, over 80 per cent of pharmaceutical and medical devices manufacturers did not have product visibility till point of care. And more than 50 per cent of them lose 1 per cent of their sales due to expiry and pilferage.

End in sight?

Representatives of large and mid-sized domestic drugmakers told the correspondent they have not asked for an extension of the deadline. A response is awaited from the platform for multinational companies. Swaminathan said the landscape was changing rapidly and about 20 companies were involved in getting the hardware and software to help drugmakers meet the deadline. There are multiple business models and small and medium companies doing contract work for larger companies would get their client's support to get up to speed with the technology, he said. Industry observers said the cost involved would be incremental, depending on the level of automation that companies wanted. Nearly 10 years since discussions on a local track and trace system for medicines began, Swaminathan was hopeful that "there is light at the end of the tunnel". (Source: Business Line)

US FDA Grants Standard Approval Of Eisai/Biogen Alzheimer's Drug



Eisai (4523.T) and Biogen's (BIIB.O) Leqembi won a coveted standard approval nod from the U.S. Food and Drug Administration on Thursday, the first Alzheimer's treatment to achieve that goal, clearing the way for wider insurance coverage of the drug. The FDA decision marks a new milestone for a fatal disease that has eluded drugmakers' efforts for decades. Trial data showed that the treatment slows progression of the brain-wasting disease by 27% for patients in the earliest stages of Alzheimer's.

The FDA also placed its strongest "boxed" safety warning on Leqembi's label, flagging the risk of potentially dangerous brain swelling for Alzheimer's drugs in the same class. Shares of Eisai tumbled in Tokyo morning trade on Friday, with analysts citing the safety warning as a negative surprise. Leqembi is an antibody designed to remove sticky deposits of a protein called amyloid beta from the brains of Alzheimer's patients. "Today we believe is a triumph for the Alzheimer's disease community, after so many years of hard work by so many scientists, physicians and clinical trial participants and their care partners," Eisai's U.S. chief executive, Ivan Cheung, said in an interview.

Leqembi received "accelerated" FDA approval in January based on its amyloid-clearing ability, but the U.S. government's Medicare health plan for people aged 65 and over had restricted coverage only to patients in a clinical trial.

Standard approval means that Leqembi will now be covered, although the Centers for Medicare and Medicaid Services (CMS) is linking reimbursement to patient participation in a health agency database, known as a registry. Since Alzheimer's is a disease of aging, most U.S. patients are insured by Medicare. "With FDA's decision, CMS will cover this medication broadly while continuing to gather data that will help us understand how the drug works," CMS Administrator Chiquita Brooks-LaSure said in a statement.

Leqembi, which is given intravenously, has a U.S. list price of $26,500 per year. Dr. Babak Tousi, a neurogeriatrician primary investigator of Leqembi clinical trials at the Cleveland Clinic, said he expects a lot of interest in the treatment, but estimated that only about 1 in 10 patients will actually qualify for the drug. Tousi said Leqembi "is not a cure," and will not turn back time on the disease, it will just slow progression. "This is just one piece of the puzzle," he said. Biogen and Eisai stock has risen since FDA granted accelerated approval to Alzheimer's drug Leqembi earlier this year

NEW LABEL

Leqembi's new label explains the need to monitor patients for potentially dangerous brain swelling and bleeding associated with amyloid-lowering antibodies. It says the risk is higher in patients with two copies of a gene, APOE4, associated with Alzheimer's, and that while genetic testing is highly recommended, it is not required. The drug's new label includes data showing that the use of certain anticoagulants with Leqembi has been linked to a risk of brain hemorrhage.

The boxed warning seems appropriate, as the risks need to be carefully considered and discussed with patients, Dr. Erik Musiek, a Washington University neurologist at Barnes-Jewish Hospital, said in an email. Eisai CEO Haruo Naito told reporters in Tokyo the pathology testing is not likely to weigh on the drug's dosage rate, and he expects the whole treatment process including testing will likely be covered by health insurance "in the future not too far".

The 7% slide in Eisai stock put it on track for its biggest one-day drop in more than a year. Even so, it has gained some 50% over the last year. Analysts at Jefferies said the FDA's unexpected decision to put the warning on the label could contribute to slow sales growth for the drug. The safety warning will also apply to Eli Lilly and Co's (LLY.N) donanemab, an experimental Alzheimer's drug that was shown to slow cognitive decline by 35% in a late-stage trial, according to a press release issued in May. Full results from that study are expected later this month.

Cheung said Eisai is expanding efforts to get health centers ready to use Leqembi, but declined to comment on how many patients have been treated with the drug so far. "People living with this fatal disease deserve the opportunity to discuss and choose, with their doctor and family, whether an FDA-approved treatment is right for them," Joanne Pike, Alzheimer's Association president and CEO, said in a statement.

A committee of external advisers to the FDA recently recommended traditional approval of the drug after an agency staff report concluded it offered a meaningful benefit to patients and said safety concerns could likely be managed. More than 6 million Americans have Alzheimer's, according to the Alzheimer's Association. Eisai has estimated that amyloid-lowering drugs would be used in some 100,000 U.S. patients during Leqembi's first three years on the market. The first FDA-approved disease-modifying Alzheimer's drug, Aduhelm, was also developed by partners Eisai and Biogen, but Medicare coverage restrictions have severely limited its use. Outside of the United States, Eisai has submitted applications for approval of Leqembi also in Japan, EU, China, Canada, Great Britain and South Korea. In Japan and China, the applications have been designated for priority review. Reporting by Deena Beasley in Los Angeles and Julie Steenhuysen in Chicago; Additional reporting by David Dolan and Kevin Buckland in Tokyo; Editing by Bill Berkrot, Matthew Lewis, Edwina Gibbs and Sherry Jacob-Phillips. (Source: Reuters)