

RSSDI Indian Diabetes

EDUCATOR JOURNAL



Theme of the Month

Mental Well-being and Diabetes

To keep Members of Diabetes Care team abreast about
DSME/DSMS - (Diabetes Self management Education/Support) Concepts

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FOREWORD

Research Society for the Study of Diabetes in India (RSSDI) founded by Prof. MMS Ahuja in the year 1972 is the biggest scientific association of healthcare professionals involved in promoting diabetes education and research in India. RSSDI is happy to collaborate with USV to support their endeavour to make India the 'Diabetes care capital of the world'. Through this collaboration, RSSDI would like to strengthen the cadre of diabetes educators by empowering them with recent updates in diabetes management helping bridge the gap between the physician and the patient. Today, the rule of 50% is prevailing in terms of awareness, detection, treatment and control in T2DM. Our aspiration is to achieve 90-90-90-90 i.e. 90% of people with diabetes should be made aware, 90% should be detected, 90% of those detected should be treated, and 90% of those treated should reach their goals.

Indian Diabetes Educator Journal (IDEJ) is the first of its kind in India, and the longest running monthly diabetes educator journal since April 2015 and continues its endeavour to spread awareness, knowledge and enable healthcare teams to manage individuals with diabetes and empower them for self-care. RSSDI IDEJ will continue to keep the members of diabetes care team abreast with concepts of Diabetes Self-Management Education/Support (DSME/S) with a reach of 44000 doctors and diabetes educators digitally.

This month's theme, "Mental Well-being and Diabetes" highlights the vital two-way relationship between mental health and diabetes. It explores how diabetes can impact mental well-being while also acknowledging that mental health issues can complicate diabetes management. The edition emphasizes the importance of fostering healthy coping strategies, providing emotional support, and ensuring access to mental healthcare to enhance overall wellness. This issue of IDEJ aims to inspire diabetes educators to adopt approaches that prioritize the mental health of individuals living with diabetes. We hope it offers valuable insights to help educators promote mental wellness in diabetes care.

We sincerely thank our contributors for making this issue delightful reading for our readers. We dedicate this journal to all the healthcare professionals who are working relentlessly towards making "India-The Diabetes Care Capital of the World."

Sincere Regards,

Dr. Sanjay Agarwal
RSSDI Secretary

Disclaimer: This Journal provides news, opinions, information and tips for effective counselling of people with diabetes. This Journal intends to empower your clinic support staffs for basic counselling of people with diabetes. This journal has been made in good faith with the literature available on this subject. The views and opinions expressed in this journal of selected sections are solely those of the original contributors. Every effort is made to ensure the accuracy of information but Hansa Medcell or USV Private Limited will not be held responsible for any inadvertent error(s). Professional are requested to use and apply their own professional judgement, experience and training and should not rely solely on the information contained in this publication before prescribing any diet, exercise and medication. Hansa Medcell or USV Private Limited assumes no responsibility or liability for personal or the injury, loss or damage that may result from suggestions or information in this book.

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Article: Frequently Asked Questions on Mental Well-being and Diabetes

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Cover Story: Silent Strain: The Interplay Between Mental Health and Diabetes



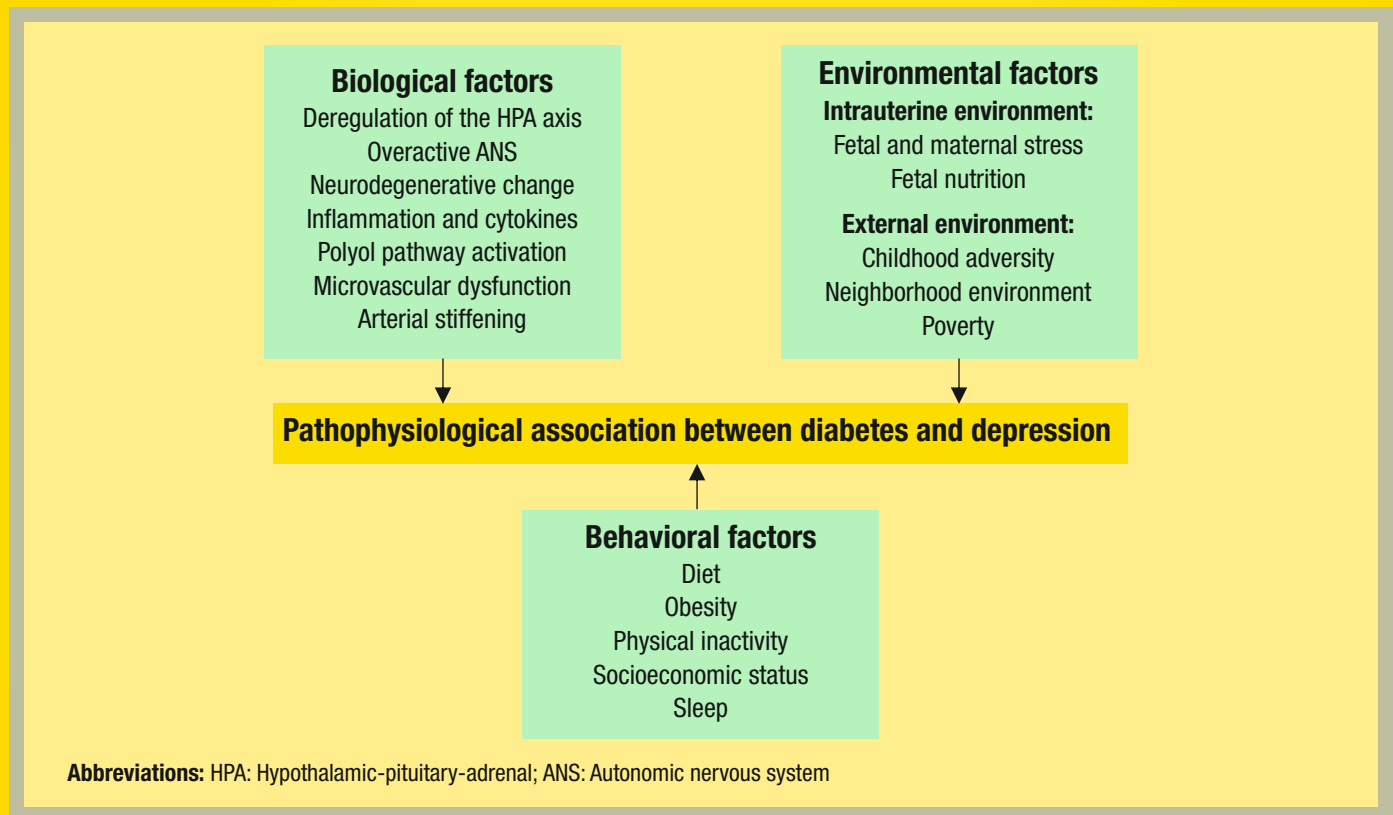
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Diabetes, a global health issue with both microvascular and macrovascular complications, significantly impacts mental health, with depression being one of the most common co-occurring conditions. Individuals with depression experience a persistently low mood for at least two weeks, along with at least five of the following symptoms:

Decreased interest or pleasure, altered sleep pattern with insomnia or hypersomnia, poor concentration, changes in appetite with weight loss or gain, lack of energy, feelings of guilt or worthlessness, psychomotor agitation, and suicidal thoughts. Studies indicate that depression prevalence is higher among those with prediabetes, undiagnosed diabetes, and previously diagnosed diabetes compared to those with normal blood glucose levels. The figure below gives an overview of the pathophysiological association between diabetes and depression.



Both have a bidirectional relationship; in addition to the pathophysiological factors involved in depression, certain antidepressants also increase the risk of diabetes. The combination of diabetes and depression intensifies healthcare challenges, as emotional distress impacts treatment adherence and self-care, with detrimental effects on glycemic control.

They also exacerbate complications, increase mortality—particularly from cardiovascular causes—and significantly increase healthcare costs due to the added strain on glycemic control, increased risk of dementia, and extended hospital stays.

The American Diabetes Association recommends integrating psychosocial care into routine diabetes management to improve quality of life and health outcomes through a collaborative, person-centered, and culturally informed approach by trained professionals. Diabetes care teams are advised to implement psychosocial screening protocols for mood concerns, stress, quality of life, resources (financial, social, family, emotional), and psychiatric history, with screenings conducted at the initial visit, periodically (at least annually) or with any change in disease, treatment, or life circumstances.

While most people with diabetes experience distress rather than mental illness, it's essential to recognize that negative emotions are not per se in need of fixing. In most cases, people learn to self-manage their emotions with the help of family, friends, and supportive healthcare providers. Here, fostering self-awareness, understanding, and normalization of emotional responses can be effective strategies for restoring emotional balance. Health providers can support patients by actively listening, showing empathy, and helping them find self-management strategies that enhance their quality of life. Tools like the World Health Organization (WHO)-5 Well-Being Index can facilitate these conversations by tracking well-being over time and identifying needs for further support.

When psychosocial concerns are identified, referrals should be made to qualified behavioral health professionals, ideally those with diabetes expertise, for evaluation and treatment. Embedding these professionals within diabetes care settings and using a collaborative team approach improves diabetes self-management, depression outcomes, and psychosocial functioning.



Resources:

1. Habib S, Sangaraju SL, Yopez D, Grandes XA, Talanki Manjunatha R. The Nexus Between Diabetes and Depression: A Narrative Review. *Cureus*. 2022;14(6):e25611. Published 2022 Jun 2. doi:10.7759/cureus.25611.
2. American Diabetes Association Professional Practice Committee; 5. Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes: Standards of Care in Diabetes—2024. *Diabetes Care* 1 January 2024; 47 (Supplement_1): S77–110. <https://doi.org/10.2337/dc24-S005>.
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Spotting the Signs: Screening Mental Well-being in Diabetes



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Diabetes management is a multifaceted endeavor, extending beyond physical health to encompass mental well-being. People with diabetes often experience psychological challenges, including diabetes distress, anxiety, and depression, which can hinder effective self-management and impact overall quality of life. Epidemiological studies have

shown that people with type 1 or type 2 diabetes face twice the risk of clinical depression compared to the general population, where prevalence is typically between 5% and 7%.

The emotional burden associated with diabetes self-management, such as continuous blood glucose monitoring, dietary restrictions, and the fear of complications, can lead to what is termed “diabetes distress.” This distress manifests as feelings of frustration, anxiety, and helplessness, which can impede adherence to treatment and affect patients' quality of life. A significant amount of psychological distress in diabetes goes unrecognized due to time constraints in busy clinics. Although many patients want to discuss mental health with their providers, some prefer confiding in family, friends, or external professionals. Integrating mental health into diabetes care is essential, with guidelines recommending regular psychological screening using standardized tools. The American Diabetes Association (ADA) advises screening at the initial visit, periodically, or with changes in treatment or life circumstances involving caregivers and family members when appropriate.



Recommended questionnaires and scales

1. Diabetes Distress Scale-17 (DDS-17): The DDS is a widely used tool that helps to measure the emotional burden of individuals living with diabetes. It consists of 17 items divided into four domains: Emotional strain from living with diabetes, stress from self-management, social pressures, and challenges with healthcare relationships. It is linked to higher glycated hemoglobin (HbA1c) levels, elevated blood pressure, and increased low-density lipoprotein (LDL) cholesterol. People with higher diabetes distress also face a 1.8-fold increase in mortality, a 1.7-fold greater risk of cardiovascular disease, and reduced quality of life.

2. Patient Health Questionnaire (PHQ-9): This 9-item scale is commonly used to screen for major depressive disorder. Given that depression is prevalent among people with diabetes, the PHQ-9 can provide valuable insights into the mental health status of patients. However, it cannot detect diabetes distress, meaning this condition may remain undiagnosed and untreated without a dedicated screening tool.

3. Generalized Anxiety Disorder 7-Item Scale (GAD-7): The GAD-7 is used to screen for anxiety disorders. Similar to the PHQ-9, it assesses the frequency of anxiety symptoms experienced over the last two weeks. High GAD-7 scores in people with diabetes can indicate significant anxiety that may interfere with diabetes management.

4. World Health Organization-Five Well-Being Index (WHO-5): This brief questionnaire consists of five items that evaluate general well-being and life satisfaction. It is useful for quickly assessing mental health and can be employed in various healthcare settings to complement diabetes-specific assessments.

5. Diabetes-Specific Quality of Life Scale (DSQOLS): This scale assesses the impact of diabetes on various aspects of life, including psychological well-being. A new version of the diabetes quality of life (DQoL) questionnaire was successfully created, retaining the concepts of “satisfaction,” “impact,” and “worry” across 13 items.

People with diabetes should undergo regular screening for psychological distress (e.g., diabetes distress, fear of hypoglycemia) and mental health disorders, with referrals to specialized care if needed. Collaborative, interprofessional teams and psychosocial interventions (e.g., cognitive behavioral therapy [CBT], motivational support, stress management, family therapy) are recommended to improve mental health, adherence to treatment, and glycemic control. Children and adolescents require specific screening protocols for depression, family distress, and body image concerns. Regular metabolic monitoring is advised for those on antipsychotic medications due to potential adverse effects. Prioritizing mental health alongside physical health enhances the quality of life for people with diabetes, promoting a more holistic approach to care.



Key points

- Diabetes distress, anxiety, and depression are common, impacting self-management and quality of life.
- ADA advises screening at the initial visit, periodically, or with changes in treatment or life circumstances, involving caregivers and family members when appropriate.
- DDS-17, PHQ-9, GAD-7, WHO-5, and DQoL scales are recommended to assess psychological well-being.
- Interprofessional teams and psychosocial interventions (e.g., CBT, motivational support, stress management) are recommended to enhance mental health, treatment adherence, and glycemic control.



Resources:

1. Diabetes and Mental Health, Robinson, David J, *et al.* *Canadian Journal of Diabetes*. Volume 42, S130–41.
2. Screening tool provides insight to the depths of diabetes-related distress (2022) DiabetesontheNet. Available at: <https://diabetesonthenet.com/journal-diabetes-nursing/screening-tool-provides-insight-to-the-depths-of-diabetes-related-distress/>
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Pharmacotherapy for Psychological Conditions and Metabolic Risk in Diabetes



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The treatment of psychological conditions often involves the use of psychotropic medications, which are essential for managing mental health disorders such as depression, anxiety, schizophrenia, and bipolar disorder. While these medications can be effective in alleviating symptoms, they also carry significant risks, particularly concerning

metabolic health. Specifically, many psychotropic medications have been linked to an increased risk of metabolic syndrome (MetS), type 2 diabetes mellitus (T2DM) and associated conditions such as cardiovascular diseases.

How psychotropic medications increase the risk of diabetes

The relationship between psychotropic medications and metabolic disturbances is well-documented in the literature. Numerous studies have shown that certain classes of medications, particularly antipsychotics, have profound effects on weight gain, insulin sensitivity, and glucose metabolism.

1. Weight gain

Many antipsychotic medications, especially second-generation (atypical) antipsychotics like olanzapine and clozapine, are associated with significant weight gain. This weight gain is not merely a cosmetic issue; it is a substantial risk factor for the development of insulin resistance and T2DM. Research indicates that patients on these medications can experience an increase in body weight by an average of 5%–10% within the first few months of treatment. For example, a study found that users of antipsychotics had a three-fold increased risk of developing T2DM compared to non-users, with this risk being apparent within the first year of treatment.



2. Insulin resistance

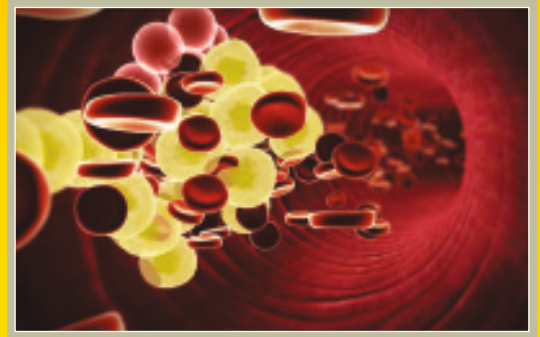
The mechanisms by which psychotropic medications contribute to insulin resistance are complex. Some medications disrupt normal glucose metabolism by impairing insulin secretion from the pancreas or increasing insulin resistance in peripheral tissues. For instance, clozapine has been shown to not only promote weight gain but also directly impair insulin secretion. This dual action significantly raises the risk of developing hyperglycemia and, eventually, T2DM.

3. Dyslipidemia

In addition to weight gain and insulin resistance, psychotropic medications can lead to dyslipidemia, which further compounds the risk for T2DM and cardiovascular diseases. Elevated triglycerides and low levels of high-density lipoprotein (HDL) cholesterol are common among patients taking certain antipsychotics.

4. Increased risk for MetS

The prevalence of MetS is markedly higher in individuals with serious mental illness compared to the general population. Patients with schizophrenia or bipolar disorder often exhibit multiple components of MetS, including obesity, hypertension, and dyslipidemia. Studies suggest that this increased prevalence is partly due to the metabolic side effects of antipsychotic medications.



Conclusion

The use of psychotropic medications plays a significant role in increasing the risk of MetS and type 2 diabetes among individuals with psychological conditions, highlighting the importance of monitoring metabolic health in these individuals. While management strategies such as lifestyle modifications and medication adjustments are crucial, understanding the inherent risks associated with psychotropic pharmacotherapy is essential for healthcare providers to ensure comprehensive care for their patients. Addressing both mental health needs and metabolic risks can lead to better overall health outcomes in this vulnerable population.

Key points

- Psychotropic medications for mental health conditions can increase the risks of diabetes and MetS, mainly through weight gain, insulin resistance, and dyslipidemia.
- Second-generation antipsychotics, like olanzapine and clozapine, are especially linked to these effects.
- Regular metabolic monitoring and lifestyle adjustments are crucial for managing these risks and improving patient outcomes.

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1. Bobo WV, Cooper WO, Stein CM, *et al.* Antipsychotics and the risk of type 2 diabetes mellitus in children and youth. *JAMA Psychiatry*. 2013;70(10):1067–75.
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Key Risk Factors for Depression in Diabetes



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Individuals with diabetes are more likely to develop psychological issues, such as depression. Studies have shown that they have a 24% increased risk of developing depression. The interplay between diabetes and depression can lead to prolonged depressive episodes and a higher likelihood of recurrence. Some studies report a higher prevalence of depression among younger

individuals with diabetes, while others show a greater prevalence in older adults. For younger individuals, this may be due to greater exposure to stress, conflicts, and fear of the unknown future. Among older individuals, the increased risk may stem from the long duration of the disease and a higher likelihood of diabetes-related complications.

The risk factors for developing depression in individuals with diabetes are as follows:

- Female sex
- Adolescents/young adults and older adults
- Poverty
- Few social supports
- Stressful life events
- Poor glycemic control, particularly recurrent hypoglycemia
- Higher illness burden
- Longer duration of diabetes
- Presence of long-term complications



The clinical condition of individuals with diabetes is worsened by comorbid depression. This may be due to the accompanying lethargy, which reduces motivation for self-care, leading to decreased physical and psychological fitness, increased use of healthcare services, and lower adherence to prescribed regimens. Additionally, depression appears to increase cardiovascular mortality. One study reported that the factor most strongly associated with the highest prevalence of depression was the need for insulin.

Depression can intensify the symptom burden for individuals with diabetes by approximately fourfold. Therefore, understanding these risk factors is essential for healthcare providers to identify those at greater risk for depression.



Resources:

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Interview with Dr. Mayura Kale



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Dr. Mayura Kale is a highly respected consultant diabetes specialist at Dr. Kale's Diabetes and Psychiatry Clinic in Aurangabad, bringing over 20 years of experience to her work. Known for her holistic approach, she focuses on managing diabetes and lifestyle disorders through sustainable health practices and individualized care. Her dedication to patient education and long-term health outcomes has made a positive impact on countless lives. Dr. Kale has served as a consultant at a 150-bed multispecialty hospital, presented at conferences, and lectured extensively. She has also been a brand ambassador for diabetes prevention campaigns and volunteered during the COVID-19 pandemic, impacting thousands of lives with her compassionate, patient-centered care.

Mental Well-being and Diabetes



1. What are the most common mental health challenges faced by individuals with diabetes?

Ans. Depression, anxiety, and diabetes distress are a few common health challenges faced by individuals with diabetes.



2. In your experience, how often do you see conditions like depression, anxiety, or other psychological disorders in your patients with diabetes, and how do these affect their overall health?

Ans. Depression, anxiety, and other psychological disorders are observed in as many as 30%–40% of patients with diabetes.

Individuals with diabetes often experience feelings of frustration, guilt, and anxiety related to managing their condition, which can lead to emotional exhaustion and burnout. High levels of diabetes distress are associated with lower self-care behaviors, such as reduced physical activity, unhealthy eating habits, and neglecting medication adherence. Those experiencing diabetes distress tend to have higher glycated hemoglobin (HbA1c) levels, indicating poor glycemic control, which increases the risk of complications. The stress of managing diabetes can lead to feelings of isolation and avoidance of social interactions, further exacerbating emotional difficulties. Managing diabetes can strain personal relationships due to mood swings. The constant demands of self-care can make it challenging for individuals to maintain healthy connections with others.



Overall, diabetes can create a cycle that negatively affects both physical health and emotional well-being.

3. What advice do you have for patients who experience emotional burnout from managing their diabetes on a daily basis?

Ans. I usually advise patients to incorporate relaxation techniques like deep breathing, yoga, or mindfulness in their daily routine to help manage stress levels. Sharing feelings with friends, family, or support groups is a good way to reduce burnout. Talking about their experiences and challenges can alleviate some emotional burdens and help them feel less isolated. Sometimes, it is advisable to avoid high expectations regarding blood glucose levels. Focusing on smaller, achievable goals can reduce stress. This could mean relaxing their targets or reducing how often they check blood glucose after consultation with the healthcare team. Engaging in activities that bring them joy and relaxation, such as hobbies, is encouraged. Individuals with diabetes, especially with type 1 diabetes, can be encouraged to join support forums or groups to share experiences and coping strategies. If feelings of distress persist, patients can be referred to a mental health professional who understands diabetes-related issues.



4. How can family, friends, and caregivers support the mental well-being of someone with diabetes?

Ans. Family and friends should be good listeners and allow an individual with diabetes to express their feelings, experiences, and challenges about living with diabetes. They should remember that mood swings may occur due to fluctuations in blood glucose levels and offer support without criticism. Knowledge about diabetes enables the caregiver to provide informed support and encouragement. Caregiver should reinforce that the individual with diabetes is not alone in managing his/her condition. Caregivers should also adopt healthy eating and exercise habits for individuals with diabetes. This shared commitment can enhance motivation and make lifestyle changes more enjoyable.

Organizing activities that promote physical health, such as walking or cooking healthy meals together, can serve as bonding experiences. Acknowledge their successes, no matter how small. Suggest stress-reducing activities like yoga, mindfulness, or even watching a funny movie together. By implementing these strategies, family and friends can significantly enhance the optimism of someone living with diabetes, contributing to better emotional health and improved management of the condition.



5. How do you envision the future role of mental healthcare in the treatment and management of diabetes?

Ans. Future diabetes care will likely include regular mental health assessments as part of standard care protocols. Utilizing standardized questionnaires can help identify patients at risk for mental health issues, allowing for timely interventions. Interventions that promote psychological well-being, such as mindfulness-based therapies and resilience training, are expected to become common practice. These programs will enhance self-efficacy and motivation in diabetes self-management, leading to better glycemic control and overall health outcomes. The use of digital tools and applications for monitoring mental health will likely increase.



Personalized Dietary Intervention to Improve Diabetes Outcomes: A Doctor's Experience on the MyCare Patient Support Program



Dr. Priyanka Shah

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An 18-year-old girl with type 1 diabetes was managed by Dr. Priyanka Shah.

Here's what Dr. Priyanka Shah has to say:

An 18-year-old girl with type 1 diabetes presented with uncontrolled blood glucose levels. Her HbA1c was 11.2%, fasting blood glucose levels were 215 mg/dL, and postprandial blood glucose levels were 306 mg/dL. She was taking 64 units of bolus insulin and 46 units of basal insulin. A detailed history revealed unhealthy eating habits, including a high intake of refined carbohydrates and junk foods of poor nutritional value, which contributed to her elevated blood glucose levels.

To address these concerns, MyCare Diabetes Educator (MDE), Ms. Khushboo Tilwani, guided her in improving her eating habits. She played a pivotal role in educating her about the effects of refined carbohydrates and suggested healthier, low glycemic index alternatives to support both glucose control and ensure adequate nutrition. She also advised easy ways to include sufficient protein in her meals.

She recommended a personalized meal plan tailored to the insulin regimen. This meal plan helped synchronize her food intake with insulin action, reducing blood glucose spikes. By aligning meals with insulin doses, it simplified her diabetes management, making insulin therapy more predictable and less burdensome. This structured approach enhanced her confidence and improved her adherence to insulin injections as well.

She was instructed to monitor her blood glucose levels regularly and maintain detailed records. With these modifications, her HbA1c dropped to 8.5%, and her fasting and postprandial glucose levels reduced to 115 mg/dL and 85 mg/dL, respectively. As a result, her insulin requirements also decreased to 50 units of bolus insulin and 40 units of basal insulin. Through personalized dietary intervention, consistent monitoring, and a positive approach to health, she has made remarkable progress. She now adheres to a structured meal plan that ensures balanced nutrition and has significantly reduced her need for higher insulin dosages.



MDE Khushboo Tilwani

NDEP and T1DE Certified Diabetes Educator

Here's what MDE Khushboo Tilwani has to say:

This story is a testament to the power of personalized dietary intervention in managing type 1 diabetes. It exemplifies the vital role of dietitians and diabetes educators in enhancing patient outcomes and serves as an encouraging example for young individuals battling similar challenges.



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*PWD: People with Diabetes

In T2DM Uncontrolled on Dual OAD's,

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Dapagliflozin 10 MG + Sitagliptin 100 MG + Metformin 500 MG XR



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Abridged Prescribing Information

UDAPA-TRIO Forte, UDAPA-TRIO, Dapagliflozin, Sitagliptin & Metformin Hydrochloride Extended Release Tablets

Composition: Dapagliflozin 10 mg, Sitagliptin 100 mg & Metformin Hydrochloride Extended Release 1000 mg tablets Dapagliflozin propanediol monohydrate eq. To Dapagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Eq. Sitagliptin 100 mg Metformin Hydrochloride IP (as Extended Release) 1000 mg Dapagliflozin 10 mg, Sitagliptin 100 mg & Metformin Hydrochloride Extended Release 1000 mg tablets Dapagliflozin propanediol monohydrate eq. To Dapagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Eq. Sitagliptin 100 mg Metformin Hydrochloride IP (as Extended Release) 500 mg **Indication:** It is indicated as an adjunct to diet and exercise to improve Glycemic Control adults with type 2 diabetes mellitus **Recommended Dosage:** As directed by the physician.

Method of Administration: Oral **Adverse Reactions:** Most common adverse reactions reported are: Dapagliflozin - Female genital mycotic infections, Nasopharyngitis, Urinary tract infections. Sitagliptin - Upper respiratory tract infection, nasopharyngitis and headache. Metformin - Diarrhea, nausea/vomiting, flatulence, anorexia, indigestion, abdominal discomfort, and headache. **Warnings and Precautions:** Dapagliflozin: Volume depletion; Ketoacidosis in patients with Diabetes Mellitus; Uronephritis and Pyelonephritis; Hypoglycemia; Genital mycotic infections. Sitagliptin: General: Sitagliptin should not be used in patients with type 1 diabetes or for the treatment of Diabetic Ketoacidosis. Acute pancreatitis. Hypoglycemia is used in combinations when combined with other anti-hyperglycemic medicinal product. Renal impairment. Hypersensitivity reactions including anaphylaxis, angioedema, and exfoliative skin conditions - Steven Johnson syndrome; Bullous pemphigoid. Metformin Hydrochloride: Lactic acidosis; In case of dehydration (severe diarrhea or vomiting, fever or reduced fluid intake), metformin should be temporarily discontinued and contact with a healthcare professional is recommended. **Contraindications:** Hypersensitivity to the active substance of Dapagliflozin, Sitagliptin & Metformin or to any of the excipients listed. Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis). Diabetic ketoacidosis. Severe renal failure (eGFR < 30 ml/min). Acute conditions with the potential to alter renal function such as: Dehydration, Severe infection, Shock; Acute or chronic disease which may cause tissue hypoxia such as: Cardiac or respiratory failure, Recent myocardial infarction, Shock, Renal impairment, Acute intoxication, Alcoholism. **Use in special population:** Pregnant women: Due to lack of human data, drugs should not be used during pregnancy. Lactating women: It should not be used during breastfeeding. Pediatric patients: The safety and efficacy of drugs has not yet been established. No data is available. Geriatric Patients: In patients >65 years, it should be used with caution as age increases. For Additional Information/Full prescribing information, please write to us: USV Private Limited, Arvind Wihal Gandhi Chowk, B.S.D Marg, Govandi, Mumbai - 400088 Last updated on 02/04/2024.

Reference:
1. Böhm AK et al. Regimen simplification and medication adherence: Fixed-dose versus loose-dose combination therapy for type 2 diabetes. *PLoS one*. 2021 May 4;16(5):e0250993; 2. DAPAGLIFLOZIN, SITAGLIPTIN, AND METFORMIN ER FDC IN INDIAN TYPE 2 DIABETES MELLITUS PATIENTS WITH INADEQUATE GLYCEMIC CONTROL ON METFORMIN MONOTHERAPY: A MULTICENTER RANDOMIZED Double-Blind Parallel Study" oral paper presented in Diabetes India - Jan 2024; 3. McKinnon JJ et al. Dapagliflozin in patients with heart failure and reduced ejection fraction. *New England Journal of Medicine*. 2019 Nov;381(21):1995-2008; 4. Wiviott SD et al. Dapagliflozin and cardiovascular outcomes in type 2 diabetes. *New England Journal of Medicine*. 2019 Jan 24;380(4):347-57; 5. Green JB, Bethel MA, Armstrong PW, Buse JB, Engel SS, Garg J, Josse R, Kaufman KD, Raglin J, Ram S, Lachin JM. Effect of sitagliptin on cardiovascular outcomes in type 2 diabetes. *New England Journal of Medicine*. 2015 Jul;373(3):232-42; 6. Bevilacqua J, Kotev M, Kroupova K, Wohlhart P, Kovar J, Frankova J, Hegerova M, Hoskova L, Hoskova E, Pelikanova T, Jarelim P. Metformin treatment is associated with improved outcome in patients with diabetes and advanced heart failure (HIFEF). *Scientific Reports*. 2022 Jul;12(1):13038; 7. Heerspink HJ et al. Dapagliflozin in patients with chronic kidney disease. *New England Journal of Medicine*. 2020 Oct 8;383(15):1436-46; 8. Tanner C et al. Metformin: time to review its role and safety in chronic kidney disease. *Medical Journal of Australia*. 2019 Jul;211(1):37-42.



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Diabetes Experts²

Ref: 1. Ravikumar et al Cardiology and Cardiovascular Medicine, 2023, 7, 141-144, 1

Abridged Prescribing Information

Composition: Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin (10 mg) + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (100 mg). **Indications:** For the treatment of type 2 diabetes mellitus inadequately controlled on Metformin monotherapy. **Recommended Dosage:** As directed by the physician. **Method of Administration:** Oral. **Adverse Reactions:** Female genital mycotic infections, nasopharyngitis, and urinary tract infections are most common adverse reactions associated with dapagliflozin. While, upper respiratory tract infection, nasopharyngitis, and headache are most common adverse reactions associated with sitagliptin. **Warnings and Precautions:** **Risk of Volume Depletion in Elderly:** Before initiating Dapagliflozin and Sitagliptin, assess volume status and renal function in the elderly. **Assess:** patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected, discontinue UDAPA-S, evaluate and treat promptly. **Before initiating UDAPA-S, consider risk factors for ketoacidosis.** Patients on UDAPA-S may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. **Dehydration and Pyelonephritis:** Evaluate for signs and symptoms of urinary tract infections and treat promptly, if indicated. **Hypoglycemia:** Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with Dapagliflozin and Sitagliptin. **Neurologic Toxicity of the Perium:** Serious, life-threatening cases have occurred in patients with diabetes, both females and males. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perianal area, along with fever or malaise. If suspected, institute prompt treatment. **Genital Mycotic Infections:** Monitor and treat if indicated. **Contraindications:** Patients with a history of hypersensitivity reaction to the active substance or to any of the excipients. In patients with varying degrees of renal impairment, adjusting the dosage is advised based on the severity of the condition. Prohibited medications include strong CYP2C8 inhibitors/reducers, drugs increasing/decreasing hypoglycemic action, drugs known to cause QT prolongation, or other oral hypoglycemic agents other than study medications.

For additional information, full prescribing information, please write to us:

USV Private Limited, Arvind Vitthal Gandhi Chowk, B-5/B Marg, Govandi, Mumbai - 400088

Dated on 28th March 2024

PV - In case of any adverse events, kindly contact: pv@usv.in

For the use only of Registered Medical Practitioner or a Hospital or a Laboratory only



USV Private Limited,
Arvind Vitthal Gandhi Chowk, B-5/B Marg, Station Road, Govandi East, Mumbai - 400 088, India.

Understanding Psychological Care in Type 1 Diabetes Mellitus



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Type 1 diabetes mellitus (T1DM) requires both physical and psychological care, especially for children, adolescents, and young adults. Mental well-being is the key to successful diabetes management and better health outcomes.

Interventions recommended to support young individuals with T1DM

1. Family-based and clinic-based psychosocial interventions

Family-based therapy with goal-setting, problem-solving, and shared responsibility reduces conflict and clear communication and enhances glycemic control. In clinic visits, family teamwork and psychoeducational support from a “care ambassador” further boost parental involvement, reduce hypoglycemia, and minimize emergency visits. Together, these strategies lead to better diabetes management for younger children.

2. Peer support programs

Coping skills training in peer groups for adolescents and school-age children improves glycemic control, reduces diabetes-related stress, and enhances quality of life and social relationships.



3. Cognitive behavioral therapy (CBT)

CBT helps individuals identify and change negative thought patterns, making it effective for managing diabetes-related distress and anxiety around blood glucose monitoring or insulin use. It also builds problem-solving skills, empowering young people to better handle diabetes challenges.

4. Motivational interviewing (MI)

MI is a counseling approach that enhances a patient's motivation to engage in their treatment. It's especially beneficial for adolescents who may struggle with self-management. By focusing on the patient's personal values and goals, MI fosters self-efficacy, encouraging them to take ownership of their diabetes care.

5. Technology-assisted interventions

Adolescents with diabetes benefit from behavioral interventions via Skype, telehealth, text messaging, and chat rooms. More complex online programs targeting glycemic control and emotional regulation have increased blood glucose monitoring and improved working memory and glycemic control, especially for those with emotional challenges. Digital tools like apps and online games help foster behavior change and improve self-efficacy but show mixed results on other health and psychological outcomes.

Incorporating psychological care into T1DM management is crucial for young individuals. Interventions like CBT and peer support address emotional challenges, improving both mental well-being and diabetes outcomes with early and consistent support.



Resource:

- de Wit M, Gajewska KA, Goethals ER, *et al.* Psychological care of children, adolescents, and young adults with diabetes. *ISPAD Clinical Practice Consensus Guidelines 2022*. Amsterdam UMC, Vrije Universiteit Amsterdam; 2022.

Psychological Treatments: The Role of Cognitive Behavioral Therapy in Diabetes Management



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Introduction

Diabetes, a rapidly expanding global chronic disease, imposes a significant psychological toll on individuals. Self-management activities such as dietary modifications, physical exercise, adherence

to medications or insulin, self-monitoring, and regular clinic visits can be demanding. Maintaining motivation for these tasks can be challenging and often results in frustration or burnout.

Psychological challenges in diabetes management

The psychological burden of diabetes can stem from a variety of factors, including:

- Biological aspects, such as fluctuations in blood glucose levels that impact mood and mental clarity.
- Social influences like stigma or familial expectations.
- The demands of daily management, which contribute to feelings of stress and exhaustion.



Psychotherapeutic interventions

Several psychotherapeutic approaches, including motivational interviewing, mindfulness-based therapies, and counseling, have been found effective in supporting behavior change. Among these, cognitive behavioral therapy (CBT) stands out for its widespread application and proven efficacy.

CBT

CBT is a focused, structured psychological treatment that emphasizes understanding and modifying current thought patterns and behaviors. Unlike other psychological treatments, CBT is typically time-limited and is designed to address specific problems in a practical, hands-on manner.

Core principles of CBT

1. Psychological issues are often rooted in maladaptive thought patterns.
2. Learned, unproductive behaviors contribute to psychological problems.
3. Individuals can develop healthier coping strategies, leading to symptom relief and improved daily functioning.



Effectiveness of CBT in diabetes management

Over recent decades, extensive research has highlighted the effectiveness of CBT in addressing the psychological aspects of chronic illnesses, including diabetes. Key findings include:

- **Psychoeducation and motivation:** CBT-based interventions educate individuals about their conditions, increase their understanding, and help overcome negative thought patterns.
- **Reduction of psychological distress:** CBT significantly reduces diabetes-related distress, depression, and anxiety, leading to improved quality of life.
- **Enhanced self-care and adherence:** CBT has shown to improve adherence to treatment plans and self-care behaviors, positively impacting glycemic control.
- **Promotion of physical activity:** CBT techniques can help boost motivation for physical activity, further aiding glucose management.
- **Improved emotional regulation:** Patients undergoing CBT often report better emotional control, enhanced motivation, and a more positive outlook.

CBT techniques and strategies



CBT employs various techniques, including:

Cognitive strategies

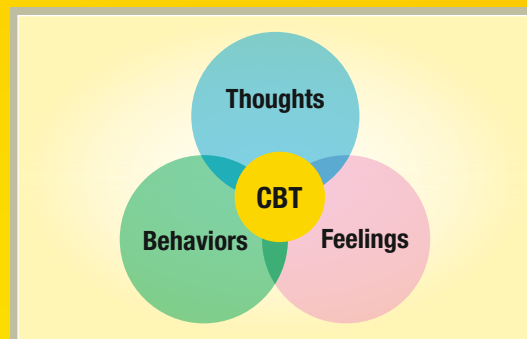
1. Recognizing and re-evaluating distorted thinking that contributes to emotional distress.
2. Gaining a deeper understanding of others' behaviors and motivations.
3. Utilizing problem-solving skills to tackle challenging situations.
4. Building self-confidence and self-efficacy.

Behavioral techniques

1. Facing fears head-on rather than avoiding them.
2. Role-playing to prepare for potentially stressful interactions.

Key points

- Diabetes has a substantial psychological impact, with self-management tasks often leading to frustration and burnout.
- Psychological challenges in diabetes stem from biological factors, social pressures, and the overall burden of disease management.
- CBT is a highly effective psychotherapeutic approach for improving mental health outcomes in individuals with diabetes.
- CBT helps modify thought patterns and behaviors through targeted strategies, which include recognizing and reframing negative thinking, problem-solving, and exposure to feared situations.
- Research supports CBT's role in reducing diabetes distress, depression, and anxiety, while enhancing quality of life, treatment adherence, and physical activity.



Resources:

1. Harvey JN. Psychosocial interventions for the diabetic patient. *Diabetes Metab Syndr Obes.* 2015;8:29–43. Published 2015 Jan 9. doi:10.2147/DMSO.S44352
2. Abbas Q, Latif S, Ayaz Habib H, *et al.* Cognitive behavior therapy for diabetes distress, depression, health anxiety, quality of life and treatment adherence among patients with type-II diabetes mellitus: A randomized control trial. *BMC Psychiatry.* 2023;23(1):86. Published 2023 Feb 3. doi:10.1186/s12888-023-04546-w
3. American Psychological Association. Cognitive behavioral therapy. Available at: <https://www.apa.org/ptsd-guideline/patients-and-families/cognitive-behavioral.pdf>. Accessed October 25, 2024.
4. Gobin K, Mills S, Katz D. Psychotherapeutic Interventions for Type 2 Diabetes Mellitus. In: *Psychology and Path physiological Outcomes of Eating. IntechOpen*; 2021. Available from: <http://dx.doi.org/10.5772/intechopen.97653>

Work-related Stress and its Association with the Risk of Diabetes



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The International Diabetes Federation highlights that the primary need in diabetes prevention is recognizing and addressing social and environmental factors that can be modified. Traditional risk factors, such as a family history, a lack of exercise, high body weight, alcohol, smoking, and unhealthy diet, are well-established.

New evidence suggests that psychosocial stress, particularly work-related stress, may also have a considerable impact on the risk of developing type 2 diabetes mellitus (T2DM).

Stress can cause temporary hyperglycemia, even in individuals without diabetes. Under stress, the liver releases extra glucose for energy, and with chronic stress, the body may struggle to manage this glucose surge, increasing the risk of T2DM.

Link between work stress and T2DM

This link is believed to result from two primary mechanisms: The dysregulation of neuroendocrine responses and lifestyle-related factors. The body's "fight or flight" response, driven by hormones like epinephrine, growth hormone, and glucocorticoids such as cortisol, elevates glucose levels and prompts higher insulin output. These hormonal changes brought on by stress, especially those involving cortisol, may moderate this connection, eventually resulting in insulin resistance and the development of diabetes. Additionally, long-term stress may have an indirect impact on diabetes risk by influencing lifestyle decisions that contribute to the risk, such as poor eating habits and decreased physical activity.



One study examined the relationship between diabetes incidence and long work hours in a 12-year sample of workers. It concluded that long work hours did not increase the risk of developing diabetes among men. However, among women, those usually working 45 hours or more per week had a significantly higher risk of diabetes than women working between 35 and 40 hours per week.

This effect may be particularly pronounced among women, as additional responsibilities and stressors could exacerbate the impact of prolonged work hours. Another systematic review and meta-analysis of prospective cohort studies also reported similar results, with females posing a higher risk of

acquiring chronic work-related stress associated with T2DM. Nevertheless, some studies have indicated an increased risk in both men and women. Chronic burnout, marked by emotional exhaustion, physical fatigue, and cognitive weakness, is estimated to increase the risk of T2DM by 1.84 times, even after adjusting for related risk factors. Reducing long work hours may lower diabetes risk, particularly for high-risk groups, underscoring the importance of workplace strategies to manage work hours and alleviate job-related stress. These findings call attention to the importance of addressing work-related stress as a modifiable risk factor in diabetes prevention.



Considerations for public health and prevention

Public health initiatives incorporating workplace wellness programs could play a significant role in reducing the incidence of diabetes associated with occupational stress. Prevention strategies for T2DM may be more effective if psychological stress responses are identified and complemented by targeted intervention programs. There are very few studies on work stress-induced diabetes in India, but many studies have been carried out in developed countries. Longitudinal studies in this area are needed to explore the connections between work hours and work environment, in combination with health behaviors and diabetes, while also considering related gender differences. This would deepen understanding of these effects and enhance prevention strategies.



Key points

- The International Diabetes Federation stresses addressing modifiable social and environmental factors in diabetes prevention alongside traditional risk factors.
- Work-related stress significantly influences the risk of developing T2DM.
- Chronic stress elevates glucose levels and may contribute to insulin resistance and diabetes, especially in those with long work hours.
- Long work hours increase diabetes risk, with chronic burnout raising the risk of T2DM by 1.84 times.
- Workplace wellness programs and longitudinal studies are essential for understanding work stress and enhancing diabetes prevention strategies.



Resources:

1. Sui H, Sun N, Zhan L, Lu X, Chen T, Mao X. Association between Work-Related Stress and Risk for Type 2 Diabetes: A Systematic Review and Meta-Analysis of Prospective Cohort Studies. *PLoS One*. 2016;11(8):e0159978. Published 2016 Aug 11. doi:10.1371/journal.pone.0159978
2. Gilbert-Ouimet M, Ma H, Glazier R, Brisson C, Mustard C, Smith PM. Adverse effect of long work hours on incident diabetes in 7065 Ontario workers followed for 12 years. *BMJ Open Diabetes Res Care*. 2018;6(1):e000496. Published 2018 Jul 2. doi:10.1136/bmjdr-2017-000496
3. Veena Prabavathy J, Sangeetha R. Stress induced type 2 diabetes mellitus among industrial workers – A review. *Res J Pharm Technol*. 2019;12(1):396–402. doi:10.5958/0974-360X.2019.00072.6.

Tech-driven Mental Health Interventions for People with Diabetes



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Managing diabetes involves a daily commitment to tracking blood glucose levels, food intake, and physical activity, often leading to stress, anxiety, and depression. Fortunately, technology-driven interventions are making it easier for people with diabetes to manage both physical and mental health aspects, fostering emotional resilience and empowerment.

Mobile apps for holistic management

Some apps integrate blood glucose tracking with mood and stress monitoring. Evidence suggests that real-time app feedback encourages positive self-management behaviors, reducing distress.

Telemedicine and virtual counseling

Telehealth has redefined accessibility to mental healthcare for people with diabetes. Through virtual consultations, patients can access psychologists, counselors, and certified diabetes educators to discuss diabetes-related anxiety and depression without geographical or time limitations. Telemedicine also facilitates long-term follow-ups, which are crucial for sustained mental well-being and diabetes management. Platforms offering cognitive behavioral therapy (CBT) and mindfulness-based interventions via telehealth have shown effectiveness in reducing diabetes-related distress and improving quality of life.



Wearable devices and predictive analytics

Wearables like the smartwatch now offer tools for monitoring not just physical activity and sleep but also physiological indicators of mental stress, such as heart rate variability. When combined with artificial intelligence (AI)-driven analytics, these devices can predict and alert users to patterns of distress, allowing for timely interventions. Wearable's continuous monitoring supports patients in maintaining consistent routines and recognizing early signs of stress or burnout.

CBT and gamified support systems

CBT platforms adapted for diabetes provide coping strategies through a structured, evidence-based approach, addressing mental health challenges unique to diabetes. Some programs even incorporate gamification to make therapy more engaging, using challenges and reward systems to motivate users for both mental and physical health goals.

By combining technology with personalized mental health strategies, these interventions provide people with diabetes access to resources that previously required in-person visits. These advancements support emotional resilience and help patients feel more empowered in their diabetes management journey.



Resources:

1. Sherifali D, Whitmore C, Naeem F, *et al.* Technology-Enabled Collaborative Care for Type-2 Diabetes and Mental Health (TECC-D): Findings From a Mixed Methods Feasibility Trial of a Responsive Co-Designed Virtual Health Coaching Intervention. *Int J Integr Care*. 2024;24(1):12. Published 2024 Feb 16. doi:10.5334/ijic.7608
2. Adeel, Ayesha & Kannangara, Chathu & Bharaj, Harni & Basu, Ambar & Green, Barrie. New Technologies and Interventions to Improve the Mental Health of People with Diabetes, 2023. Proceedings of ICACTCE'23 –The International Conference on Advances in Communication Technology and Computer Engineering (pp.753–760). 10.1007/978-3-031-37164-6_53.
3. Varela-Moreno E, Carreira Soler M, Guzmán-Parra J, *et al.* Effectiveness of eHealth-Based Psychological Interventions for Depression Treatment in Patients With Type 1 or Type 2 Diabetes Mellitus: A Systematic Review. *Front Psychol*. 2022;12:746217.

Frequently Asked Questions on Mental Well-being and Diabetes



Dr. Sunil Bhojane

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Thane

1. My 15-year-old son has type 1 diabetes and is currently preparing for his 10th board exams. His blood glucose levels have been consistently high despite following his usual insulin routine and diet plan. Could the stress and the pressure of exams be causing these spikes in his blood glucose? If yes, how do we manage it?

Ans. Yes, exam stress can indeed contribute to elevated blood glucose levels. Acute stress triggers the release of stress hormones like adrenaline and cortisol, which signal the liver to release stored glucose, leading to higher blood glucose levels. In teens with type 1 diabetes, their body's inability to produce insulin to counterbalance these spikes can lead to sustained hyperglycemia. Exam-related anxiety, lack of sleep, and reduced physical activity due to increased study time can further complicate blood glucose management.



Tips to manage stress-induced hyperglycemia

- **Encourage regular relaxation techniques like deep breathing or meditation:** Encourage regular relaxation methods such as deep breathing or short mindfulness meditation breaks.
- **Ensure a balanced diet and hydration:** Avoid snacking on unhealthy foods and intake of any high glycemic index foods that are known to increase glucose levels.
- **Regularly monitor blood glucose levels:** Increased monitoring allows for timely adjustments in insulin.
- **Adjust insulin dosage:** Given that his glucose levels are running higher than usual, it may be necessary to adjust his insulin dose. Consult his healthcare provider for personalized advice on dosage changes during high-stress periods.
- **Encourage physical activity if possible:** Light exercises, like a short walk, stretching, and chair exercises, can help lower blood glucose and relieve stress.

Managing both mental health and diabetes during high-stress periods is essential to prevent long-term complications.



2. I'm a 45-year-old woman who has been taking antidepressants for the past 4–5 years. I've recently been diagnosed with prediabetes, and I'm concerned about whether my long-term use of antidepressants could be contributing to this new diagnosis.

Ans. Long-term use of certain antidepressants may contribute to prediabetes through several mechanisms. Studies have shown that antidepressants can impact glucose metabolism and increase the risk of developing insulin resistance, which can eventually lead to type 2 diabetes. This risk tends to rise with longer durations of antidepressant use and higher dosages.

Studies have also stated that weight gain, a common side effect of many antidepressants, can also lead to insulin resistance.

- **Monitor blood sugar levels regularly:** Regular monitoring can help track any changes in blood glucose and make timely adjustments to the treatment plan.
- **Adopt a balanced diet and exercise routine:** Eating a healthy diet and incorporating regular physical activity can significantly improve insulin sensitivity and support overall metabolic health.
- **Consider a mental health support plan:** In addition to medication, lifestyle strategies like mindfulness, counseling, and stress management techniques can support mental well-being and may also benefit blood glucose control.

Staying informed and taking proactive steps in managing both mental health and prediabetes is key to preventing progression to type 2 diabetes and ensuring long-term health.

3. My husband was diagnosed with type 2 diabetes but is in denial and refuses to follow any management plan. How can I help him understand the seriousness and importance of managing his diabetes?

Ans. Diabetes denial is a common emotional response to a diagnosis. It can stem from fear, anxiety, or even misunderstanding of the condition. Here are steps you can take to help someone move past denial and take control of their diabetes.

- **Be empathetic:** Acknowledge his feelings without judgment. Let him know that it's normal to feel overwhelmed or uncertain and that you're there to support him.
- **Educate gently:** Share clear, reliable information on the risks of unmanaged diabetes and the benefits of controlling it. Try sharing stories of others who are successfully managing diabetes to give him a hopeful perspective.
- **Start small:** Encourage simple, achievable steps like cutting sugar intake from foods and beverages, adding short, regular walks, etc.
- **Address mental health:** If he continues to struggle with acceptance, consider encouraging him to talk to a mental health professional. Therapy can provide tools for coping with the emotional side of a diabetes diagnosis and address any underlying fears or anxieties.
- **Offer support:** Join him in making healthy lifestyle changes, showing he's not alone.



Did you Know? Tomato Intake is Associated with a Low Depression Rate

The prevalence of depression and associated psychological health issues is increasing due to fast-paced living and modern lifestyles. One possible reason is the low intake of fruits and vegetables and the high intake of processed foods. This is linked to low antioxidant intake and a high intake of inflammatory foods. Fruits and vegetables are rich sources of antioxidants in the diet. A high intake of fruits and vegetables is associated with a decreased incidence of depression, owing to their antioxidant content.

Tomatoes are rich in nutrients and phytochemicals such as lycopene, potassium, iron, folate, and vitamin C. In addition to lycopene and vitamin C, tomatoes contain other antioxidants like beta-carotene, as well as phenolic compounds such as flavonoids, hydroxycinnamic acid, chlorogenic acid, homovanillic acid, and ferulic acid. Tomatoes are known to offer several health benefits, many of which are attributed to their antioxidant content.

A cross-sectional study reported that tomato intake was inversely associated with depressive symptoms. Lycopene, beta-carotene, and vitamin C—antioxidants found in tomatoes—may contribute to these benefits. Another study examined the mental health and dietary habits of 986 elderly men and women aged 70 or older. The study found that individuals who ate tomatoes, whether cooked or raw, 2–6 times per week were 46% less likely to experience depression symptoms than those who ate tomatoes only once a week or less. Tomatoes are readily available and commonly consumed in Indian cuisine. When part of a balanced diet, tomatoes can help protect against depression. It's another great reason to eat more fruits and vegetables for better health and happiness.



Resources:

1. Collins EJ, Bowyer C, Tsouza A, Chopra M. Tomatoes: An Extensive Review of the Associated Health Impacts of Tomatoes and Factors That Can Affect Their Cultivation. *Biology (Basel)*. 2022;11(2):239.
2. Sun J, Li Z, Li Y, Zhang D. Intakes of Specific Categories of Vegetables and Fruits Are Inversely Associated With Depressive Symptoms Among Adults. *J Epidemiol*. 2021;31(3):210–19.

Dia-Games

Match the following

Column A

1. Cognitive behavioral therapy

2. Tomatoes

3. Metformin

4. Hospital Anxiety and Depression Scale (HADS)

5. Elevated body mass index (BMI)

Column B

A. First-line treatment for type 2 diabetes mellitus

B. Identify and change negative thought patterns

C. Reduces depression

D. Risk factor for developing type 2 diabetes mellitus

E. Screening instrument

Answers: 1: B, 2: C, 3: A, 4: E, 5: D

In PwD Uncontrolled on Dual OADs,

Choose

UDAPA GOLD

Metformin HCL 500mg ER + Glimepiride 1/2 mg + Dapagliflozin 10 mg



Dapagliflozin, Glimepiride and Metformin Hydrochloride (Extended Release) Tablets
Composition:

Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP Eq. to Dapagliflozin 10 mg, Glimepiride IP 1mg, Metformin Hydrochloride IP (As Extended release) 500 mg. Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP Eq. to Dapagliflozin 10 mg, Glimepiride IP 2mg, Metformin Hydrochloride IP (As Extended release) 500 mg. **Indication:** As an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 Diabetes Mellitus (T2DM). **Recommended Dosage:** As directed by the Physician. **Method of Administration:** Oral. **Warnings and Precautions:** Dapagliflozin, Metformin and Glimepiride should not be used in patients with type 1 diabetes and must not be used for the treatment of diabetic ketoacidosis. **Lactic acidosis** - Lactic acidosis, a rare but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. **Hypotension** - Dapagliflozin causes intravascular volume contraction. Symptomatic hypotension can occur after initiating dapagliflozin particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²), elderly patients, or patients on loop diuretics. Before initiating dapagliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms of hypotension after initiating therapy. **Genital Mycotic Infections** - Dapagliflozin increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections. Monitor and treat appropriately. **Hypoglycemia** - Patients receiving insulin and insulin secretagogues (e.g., sulfonylureas) may be at risk for hypoglycemia. Therefore, a reduction in the dose of the sulfonylurea or insulin may be necessary. **Precautions for use:** **Pregnancy** - Limited data on Dapagliflozin, Glimepiride & Metformin Tablets use during pregnancy. Advise patients to inform their healthcare provider if pregnant or planning pregnancy before initiating treatment. **Nursing Mothers** - Udupa Gold is not recommended in breastfeeding. Hence, if you are breastfeeding, inform your doctor if you are breastfeeding or planning to breastfeed. **Pediatric Use** - The safety and effectiveness of Udupa Gold in pediatric patients under 18 years of age have not been established. **Renal Impairment Dapagliflozin** - Use of dapagliflozin is not recommended when eGFR is less than 45 mL/min/1.73 m².

Glimepiride - To minimize the risk of hypoglycemia, the recommended starting dose of glimepiride is 1 mg daily for all patients with type 2 diabetes and renal impairment.

Contraindications: Udupa Gold is contraindicated in patients with: Severe renal impairment (eGFR below 30 mL/min/1.73 m²), end stage renal disease or patients on dialysis; History of a serious hypersensitivity reaction to any of the excipients of this Tablet, dapagliflozin, such as anaphylactic reactions or angioedema, or hypersensitivity to metformin HCL, Sulfonylurea derivatives, such as glimepiride, other sulfonylureas, other sulfonamides; Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin; Hepatic insufficiency; Acute alcohol intoxication, alcoholism; Lactation.

For Additional Information/Full prescribing information, please write to us: USV Private Limited, Arvind Vithal Gandhi Chowk, B.S.D Marg, Govandi, Mumbai - 400088

Updated on 01st June'24, Expiry by 01st June'25

In T2DM Across Continuum,

**START STRONG
STAY LONG**

Glycomet®-GP0.5
Metformin Hydrochloride 500 mg SR + Glimepiride 0.5 mg

Glycomet®-GP 1
Metformin Hydrochloride 500 mg SR + Glimepiride 1 mg

Glycomet®-GP 2
Metformin Hydrochloride 500 mg SR + Glimepiride 2 mg

Glycomet®-GP0.5 FORTE
Metformin Hydrochloride 1000 mg SR + Glimepiride 0.5 mg

Glycomet®-GP 1 FORTE
Metformin Hydrochloride 1000 mg SR + Glimepiride 1 mg

Glycomet®-GP 3/850
Metformin Hydrochloride 850 mg SR + Glimepiride 3 mg

Glycomet®-GP 2/850
Metformin Hydrochloride 850 mg SR + Glimepiride 2 mg

Glycomet®-GP2 FORTE
Metformin Hydrochloride 1000 mg SR + Glimepiride 2 mg

Glycomet®-GP3 FORTE
Metformin Hydrochloride 1000 mg SR + Glimepiride 3 mg

Glycomet®-GP4 FORTE
Metformin Hydrochloride 1000 mg SR + Glimepiride 4 mg



Abridged Prescribing Information

Active Ingredients: Metformin hydrochloride (as sustained release) and glimepiride tablets. **Indication:** For the management of patients with type 2 diabetes mellitus when diet, exercise and single agent (glimepiride or metformin alone) do not result in adequate glycaemic control. **Dosage and Administration:** The recommended dose is one tablet daily during breakfast or the first main meal. Each tablet contains a fixed dose of glimepiride and Metformin Hydrochloride. The highest recommended dose per day should be 8 mg of glimepiride and 2000mg of metformin. Due to prolonged release formulation, the tablet must be swallowed whole and not crushed or chewed. **Adverse Reactions:** For Glimepiride: hypoglycaemia may occur, which may sometimes be prolonged. Occasionally, gastrointestinal (GI) symptoms such as nausea, vomiting, sensations of pressure or fullness in the epigastrium, abdominal pain and diarrhea may occur. Hepatitis, elevation of liver enzymes, cholestasis and jaundice may occur; allergic reactions or pseudo allergic reactions may occur occasionally. For Metformin: GI symptoms such as nausea, vomiting, diarrhea, abdominal pain, and loss of appetite are common during initiation of therapy and may resolve spontaneously in most cases. Metallic taste, mild erythema, decrease in Vit B12 absorption, very rarely lactic acidosis, Hemolytic anemia, Reduction of thyrotropin level in patients with hypothyroidism, Hypomagnesaemia in the context of diarrhea, Encephalopathy, Photosensitivity, hepatobiliary disorders. **Warnings and Precautions:** For Glimepiride: Patient should be advised to report promptly exceptional stress situations (e.g., trauma, surgery, febrile infections), blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary to maintain good metabolic control. Metformin Hydrochloride may lead to Lactic acidosis; in such cases metformin should be temporarily discontinued and contact with a healthcare professional is recommended. Sulfonylureas have an increased risk of hypoglycaemia. Long-term treatment with metformin may lead to peripheral neuropathy because of decrease in vitamin B12 serum levels. Monitoring of the vitamin B12 level is recommended. Overweight patients should continue their energy-restricted diet, usual laboratory tests for diabetes monitoring should be performed regularly. **Contraindications:** Hypersensitivity to the active substance of glimepiride & Metformin or to any of the excipients listed. Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis, diabetic pre-coma). Severe renal failure (GFR<30ml/min). In pregnant women. In lactating women. Acute conditions with the potential to alter renal function (dehydration, severe infection, shock, intravascular administration of iodinated contrast agents); acute or chronic disease which may cause tissue hypoxia (cardiac or respiratory failure, recent myocardial infarction, shock); hepatic insufficiency; acute alcohol intoxication; alcoholism. **Use in a special population:** Pregnant Women: Due to a lack of human data, drugs should not be used during pregnancy. Lactating Women: It should not be used during breastfeeding. Pediatric Patients: The safety and efficacy of drugs has not yet been established. Renal impairment: A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

Additional information is available on request.

Last updated: March 13, 2023

*In case of any adverse events, kindly contact: pv@usv.in

For the use of registered medical practitioner, hospital or laboratory.*



USV Private Limited

Corvette Team

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